

CARer-ADministration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: the CARiAD open pilot RCT

Trial Close-out Participant Information Sheets

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CARer-ADministration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: the CARiAD open pilot RCT

Close out PIS Carer Continuation PB



CARiAD – Carer administration of as-needed subcutaneous medicines for breakthrough symptoms at home

Information sheet for carers

Thank you very much for taking part in the CARiAD project. We are so sorry for your loss.

As the CARiAD project is closing soon, we wanted to let you know how this affects you.

In the information you had before participating in the CARiAD project, we explained that a research nurse will visit you six to eight weeks after the person you cared for had passed away. This will still go ahead, but the way we use the information from this visit will be different as we have a duty to report our first analysis of the study information soon.

All the information about your participation up until now, and the participation of the person you cared for, will be in the first analysis of the project. The information from the research nurse visit after the person you cared for had passed away, however, will not be able to be included in this first analysis. The information is still really important to record, as it will help us to understand if it is possible to undertake a larger trial in the future.

We understand that this is a very emotionally sensitive time for you. Please do not hesitate to contact the research nurses, who are experienced palliative care professionals, should you need to.

If at any time you have questions regarding the project in general, please contact our trial manager, Stella Wright.

Thank you for taking the time to read and consider this information.

Contact details

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This study is funded by the National Institute for Health Research (NIHR) HTA (project reference 15/10/37). The views expressed are those of the author and not necessarily those of the NIHR or the Department of Health and Social Care.

CARiAD Close out PIS Carer Continuation PB (v1, 15/05/2019)

CARer-ADministration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: the CARiAD open pilot RCT

Close out PIS Dyad Intervention Withdrawal A



CARIAD – Carer administration of as-needed subcutaneous medicines for breakthrough symptoms at home

Information sheet for patients and carers

Thank you very much for taking part in the CARIAD project. As the CARIAD project is closing, we wanted to let you know how this affects you.

You were assigned to the 'new care' group, and all the information about your participation up until now will be in the analysis of the project. We are grateful for this as it will help us to understand if it is possible to undertake a larger trial in the future.

As the project is closing, we regret that you will not be able to continue with the rest of the project. From the information you had before participating in the CARIAD project you would have expected the next steps would have been that;

- the carer will be trained by the nurses to recognise breakthrough symptoms, prepare and give no-needle injections at home, and
- the carer will be asked to keep a diary of symptoms and treatments and to complete a questionnaire every other day during the trial.

These steps will now not happen. This will not affect the ongoing care from your clinical team.

We understand that this is a very emotionally sensitive time for you. We made sure that your clinical team is aware of these changes, and they will be able to talk things through with you. In addition, you can also contact the research nurses, who are experienced palliative care professionals, should you need to.

If at any time you have questions regarding the project in general, please contact our trial manager, Stella Wright.

Thank you for taking the time to read and consider this information.

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CARIAD Close out PIS Dyad Intervention Withdrawal A (v1, 15/05/2019)

CARer-ADministration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: the CARiAD open pilot RCT

Close out PIS HCP Intervention Withdrawal A

CARIAD – Carer administration of as-needed subcutaneous medicines for breakthrough symptoms at home

Information sheet for healthcare professionals

Thank you for your support for the CARIAD project. As the CARIAD project is closing, we wanted to let you know how this affects you.

A patient under your care, and their carer, are enrolled in the intervention arm of the CARIAD project. Our understanding from the local team is that the patient is currently not deemed to be in the last days of life, and that the carer has not been trained to give subcutaneous injections. As the project is closing, the dyad will be withdrawn.

The attached information sheet entitled “CARIAD Close out PIS Dyad Intervention Withdrawal A, v1, 15/05/2019” details the information the dyad will receive about study close-out procedures. Please take time to read this.

Of specific note, we carefully considered whether to raise the issue of prognostic uncertainty in the attached dyad information sheet, and decided against it for two reasons:

1. We do not want to misrepresent a patient’s specific circumstances in what needs to be a generic project information sheet, and
2. We know that discussions about prognostication, and its inherent uncertainty, are best had face to face.

In the written information the dyad had about the CARIAD project, we explained that the study was about “people nearing the end of their lives”. As such, at the time the clinical team approached the patient to take part in the CARIAD project, they believed that they fitted the study criteria (i.e. that the patient is likely in the last weeks of life). From the trial records, we note that the patient has survived longer than initially anticipated. This means that, due to project close-out, neither the patient nor the carer can participate in the project to the extent they initially expected and they will be withdrawn from the project.

They have been reassured that there will not be any effect on the care from the clinical team.

If at any time you have questions regarding the project in general, please contact our trial manager, Stella Wright.

Thank you for taking the time to read and consider this information.

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CARIAD Close out PIS HCP Intervention Withdrawal A (v1, 15/05/2019)

CARer-ADministration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: the CARiAD open pilot RCT

Close out PIS Dyad Intervention Withdrawal B



CARiAD – Carer administration of as-needed subcutaneous medicines for breakthrough symptoms at home

Information sheet for patients and carers

Thank you very much for taking part in the CARiAD project. As the CARiAD project is closing, we wanted to let you know how this affects you.

You were assigned to the 'new care' group and we note that the carer was trained to recognise breakthrough symptoms, prepare and give no-needle injections at home. All the information about your participation up until now will be in the analysis of the project. We are grateful for this as it will help us to understand if it is possible to undertake a larger trial in the future.

As the project is closing, we regret that you will not be able to continue with the rest of the project. From the information you had before participating in the CARiAD project you would have expected the next step to be that the carer will be asked to keep a diary of symptoms and treatments and to complete a questionnaire every other day during the trial. This will now not happen. It will not affect the ongoing care from your clinical team, and they will support you in giving injections in due course. They will provide you with the documents you should use.

We understand that this is a very emotionally sensitive time for you. We have made sure that your clinical team is aware of these changes, and they will be able to talk things through with you. In addition, you can also contact the research nurses, who are experienced palliative care professionals, should you need to.

If at any time you have questions regarding the project in general, please contact our trial manager, Stella Wright.

Thank you for taking the time to read and consider this information.

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CARiAD Close out PIS Dyad Intervention Withdrawal B (v1, 15/05/2019)

CARer-ADministration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: the CARiAD open pilot RCT

Close out PIS HCP Intervention Withdrawal B

CARIAD – Carer administration of as-needed subcutaneous medicines for breakthrough symptoms at home

Information sheet for healthcare professionals

Thank you for your support for the CARIAD project. As the CARIAD project is closing, we wanted to let you know how this affects you.

A patient under your care, and their carer, are enrolled in the intervention arm of the CARIAD project. Our understanding from the local team is that the patient is currently not deemed to be in the last days of life, and that the carer was trained to recognise breakthrough symptoms, prepare and give no-needle injections at home. As the project is closing, the dyad will be withdrawn.

The attached information sheet entitled “CARIAD Close out PIS Dyad Intervention Withdrawal B, version 1, 15/05/2019” details the information the dyad will receive about study close-out procedures. Please take time to read this.

Of specific note, we carefully considered whether to raise the issue of prognostic uncertainty in the attached patient information sheet, and decided against it for two reasons:

1. We do not want to misrepresent a patient’s specific circumstances in what needs to be a generic project information sheet, and
2. We know that discussions about prognostication, and its inherent uncertainty, are best had face to face.

In the written information the patient had about the CARIAD project, we explained that the study was about “people nearing the end of their lives”. As such, at the time the clinical team approached the patient to take part in the CARIAD project, they believed that they fitted the study criteria (i.e. that the patient is likely in the last weeks of life). From the trial records, we note that the patient has survived longer than initially anticipated. This means that, due to project close-out, neither the patient nor the carer can participate in the project to the extent they initially expected and they will be withdrawn from the project.

They have been reassured that there will not be any effect on the care from the clinical team.

Your clinical team may opt to support the carer in giving injectable medication in due course (i.e. when the patient reaches the last days of life). If this is the case, please remember that you will need to use local documentation to record carer-administered injections, as CARIAD trial materials may not be used.

If at any time you have questions regarding the project in general, please contact our trial manager, Stella Wright.

Thank you for taking the time to read and consider this information.



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CARiAD Close out PIS HCP Intervention Withdrawal B (v1, 15/05/2019)



CARer-ADministration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: the CARiAD open pilot RCT

Close out PIS Dyad Continuation A



CARiAD – Carer administration of as-needed subcutaneous medicines for breakthrough symptoms at home

Information sheet for patients and carers

Thank you very much for taking part in the CARiAD project. As the CARiAD project is closing soon, we wanted to let you know how this affects you.

There will be no changes to the way the project works, as explained in the information you had before participating in the CARiAD project. The only change will be in the way we use your information as we have a duty to report our first analysis of the study information soon.

All the information about your participation up until now will be in the first analysis of the project. The information from today onwards, however, will not be able to be included in this first analysis. The information is still really important to record, as it will help us to understand if it is possible to undertake a larger trial in the future.

We understand that this is a very emotionally sensitive time for you. Please do not hesitate to contact the research nurses, who are experienced palliative care professionals, should you need to.

If at any time you have questions regarding the project in general, please contact our trial manager, Stella Wright.

Thank you for taking the time to read and consider this information.

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CARer-ADministration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: the CARiAD open pilot RCT

Close out PIS Dyad Intervention Withdrawal C



CARiAD – Carer administration of as-needed subcutaneous medicines for breakthrough symptoms at home

Information sheet for patients and carers

Thank you very much for taking part in the CARiAD project. As the CARiAD project is closing, we wanted to let you know how this affects you.

You were assigned to the 'new care' group and we note that the carer was trained to recognise breakthrough symptoms, prepare and give no-needle injections at home. All the information about your participation up until now will be in the analysis of the project. We are grateful for this as it will help us to understand if it is possible to undertake a larger trial in the future.

As the project is closing, we regret that you will not be able to continue with the rest of the project. From the information you had before participating in the CARiAD project you would have expected the next step to be that the carer will be asked to keep a diary of symptoms and treatments and to complete a questionnaire every other day during the trial. This will now not happen. It will not affect the ongoing care from your clinical team, and they will support you in giving injections in due course. They will provide you with the documents you should use.

We understand that this is a very emotionally sensitive time for you. We have made sure that your clinical team is aware of these changes, and they will be able to talk things through with you. In addition, you can also contact the research nurses, who are experienced palliative care professionals, should you need to.

If at any time you have questions regarding the project in general, please contact our trial manager, Stella Wright.

Thank you for taking the time to read and consider this information.

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CARiAD Close out PIS Dyad Intervention Withdrawal C (v1, 15/05/2019)

CARer-ADministration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: the CARiAD open pilot RCT

Close out PIS HCP Intervention Withdrawal C

CARIAD – Carer administration of as-needed subcutaneous medicines for breakthrough symptoms at home

Information sheet for healthcare professionals

Thank you for your support for the CARIAD project. As the CARIAD project is closing, we wanted to let you know how this affects you.

A patient under your care, and their carer, are enrolled in the intervention arm of the CARIAD project. Our understanding from the local team is that the patient is deemed to be in the last days of life, and that the carer was trained to recognise breakthrough symptoms, prepare and give no-needle injections at home. As the project is closing, the dyad will be withdrawn.

The attached information sheet entitled “CARIAD Close out PIS Dyad Intervention Withdrawal C, version 1, 15/05/2019” details the information the dyad will receive about study close-out procedures. Please take time to read this.

Of specific note, we carefully considered whether to raise the issue of prognostic uncertainty in the attached patient information sheet, and decided against it for two reasons:

1. We do not want to misrepresent a patient’s specific circumstances in what needs to be a generic project information sheet, and
2. We know that discussions about prognostication, and its inherent uncertainty, are best had face to face.

In the written information the patient had about the CARIAD project, we explained that the study was about “people nearing the end of their lives”. As such, at the time the clinical team approached the patient to take part in the CARIAD project, they believed that they fitted the study criteria (i.e. that the patient is likely in the last weeks of life). From the trial records, we note that the patient has survived longer than initially anticipated. This means that, due to project close-out, neither the patient nor the carer can participate in the project to the extent they initially expected and they will be withdrawn from the project.

They have been reassured that there will not be any effect on the care from the clinical team.

Your clinical team has agreed to continue to support the carer in giving injectable medication. Please remember that you will now need to use local documentation to record carer-administered injections, as CARIAD trial materials may not be used.

If at any time you have questions regarding the project in general, please contact our trial manager, Stella Wright.

Thank you for taking the time to read and consider this information.



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CARiAD Close out PIS HCP Intervention Withdrawal C (v1, 15/05/2019)

CARer-ADministration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: the CARiAD open pilot RCT

Close out PIS Dyad Continuation B



CARiAD – Carer administration of as-needed subcutaneous medicines for breakthrough symptoms at home

Information sheet for patients and carers

Thank you very much for taking part in the CARiAD project. As the CARiAD project is closing soon, we wanted to let you know how this affects you.

There will be no changes to the way the project works, as explained in the information you had before participating in the CARiAD project. The only change will be in the way we use your information as we have a duty to report our first analysis of the study information soon.

All the information about your participation up until now will be in the first analysis of the project. To ensure that this happens, the nurses will collect any diaries you have used so far, and give you fresh copies to use. The information from today onwards will not be able to be included in this first analysis. However, it is still really important to record, as it will help us to understand if it is possible to undertake a larger trial in the future.

We understand that this is a very emotionally sensitive time for you. Please do not hesitate to contact the research nurses, who are experienced palliative care professionals, should you need to.

If at any time you have questions regarding the project in general, please contact our trial manager, Stella Wright.

Thank you for taking the time to read and consider this information.

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CARer-ADministration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: the CARiAD open pilot RCT

Close out PIS Dyad Intervention Withdrawal D



CARiAD – Carer administration of as-needed subcutaneous medicines for breakthrough symptoms at home

Information sheet for patients and carers

Thank you very much for taking part in the CARiAD project. As the CARiAD project is closing, we wanted to let you know how this affects you.

You were assigned to the 'new care' group and we note that the carer was trained to recognise breakthrough symptoms, prepare and give no-needle injections at home. All the information about your participation up until now will be in the analysis of the project. We are grateful for this as it will help us to understand if it is possible to undertake a larger trial in the future.

As the project is closing, we regret that you will not be able to continue with the rest of the project. From the information you had before participating in the CARiAD project you would have expected the next step to be that the carer will be asked to keep a diary of symptoms and treatments and to complete a questionnaire every other day during the trial. This will now not happen. It will not affect the ongoing care from your clinical team, and they will continue to support you in giving injections. They will provide you with the documents you should use.

We understand that this is a very emotionally sensitive time for you. We have made sure that your clinical team is aware of these changes, and they will be able to talk things through with you. In addition, you can also contact the research nurses, who are experienced palliative care professionals, should you need to.

If at any time you have questions regarding the project in general, please contact our trial manager, Stella Wright.

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CARer-ADministration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: the CARiAD open pilot RCT

Close out PIS HCP Intervention Withdrawal D

CARIAD – Carer administration of as-needed subcutaneous medicines for breakthrough symptoms at home

Information sheet for healthcare professionals

Thank you for your support for the CARIAD project. As the CARIAD project is closing, we wanted to let you know how this affects you.

A patient under your care, and their carer, are enrolled in the intervention arm of the CARIAD project. Our understanding from the local team is that the patient is in the last days of life, and that the carer has administered at least one injection. As the project is closing, the dyad will be withdrawn.

The attached information sheet entitled “CARIAD Close out PIS Dyad Intervention Withdrawal D, version 1, 15/05/2019” details the information the dyad will receive about study close-out procedures. Please take time to read this.

Of specific note, we carefully considered whether to raise the issue of prognostic uncertainty in the attached patient information sheet, and decided against it for two reasons:

1. We do not want to misrepresent a patient’s specific circumstances in what needs to be a generic project information sheet, and
2. We know that discussions about prognostication, and its inherent uncertainty, are best had face to face.

In the written information the patient had about the CARIAD project, we explained that the study was about “people nearing the end of their lives”. As such, at the time the clinical team approached the patient to take part in the CARIAD project, they believed that they fitted the study criteria (i.e. that the patient is likely in the last weeks of life). From the trial records, we note that the patient has survived longer than initially anticipated. This means that, due to project close-out, neither the patient nor the carer can participate in the project to the extent they initially expected and they will be withdrawn from the project.

They have been reassured that there will not be any effect on the care from the clinical team.

Your clinical team has agreed to continue to support the carer in giving injectable medication. Please remember that you will now need to use local documentation to record carer-administered injections, as CARIAD trial materials may not be used.

If at any time you have questions regarding the project in general, please contact our trial manager, Stella Wright.

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CARiAD Close out PIS HCP Intervention Withdrawal D (v1, 15/05/2019)

CARer-ADministration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: the CARiAD open pilot RCT

Close out PIS Dyad Usual Care Withdrawal A



CARiAD – Carer administration of as-needed subcutaneous medicines for breakthrough symptoms at home

Information sheet for patients and carers

Thank you very much for taking part in the CARiAD project. As the CARiAD project is closing, we wanted to let you know how this affects you.

You were assigned to the 'usual care' group, and all the information about your participation up until now will be in the analysis of the project. We are grateful for this as it will help us to understand if it is possible to undertake a larger trial in the future.

As the project is closing, we regret that you will not be able to continue with the rest of the project. From the information you had before participating in the CARiAD project you would have expected the next step would have been that the carer would have completed a questionnaire every other day during the trial. This will now not happen. This will not affect the ongoing care from your clinical team.

We understand that this is a very emotionally sensitive time for you. We made sure that your clinical team is aware of these changes, and they will be able to talk things through with you. In addition, you can also contact the research nurses, who are experienced palliative care professionals, should you need to.

If at any time you have questions regarding the project in general, please contact our trial manager, Stella Wright.

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CARiAD Close out PIS Dyad Usual Care Withdrawal A (v1, 15/05/2019)

CARer-ADministration of as-needed subcutaneous medication for breakthrough symptoms in home-based dying patients: the CARiAD open pilot RCT

Close out PIS HCP Usual Care Withdrawal A

CARIAD – Carer administration of as-needed subcutaneous medicines for breakthrough symptoms at home

Information sheet for healthcare professionals

Thank you for your support for the CARIAD project. As the CARIAD project is closing, we wanted to let you know how this affects you.

A patient currently under your care, and their carer, are enrolled in the usual care arm of the CARIAD project. As the project is closing, the dyad will be withdrawn.

The attached information sheet entitled “CARIAD Close out PIS Dyad Usual Care Withdrawal A, version 1, 15/05/2019” details the information the dyad will receive about study close-out procedures. Please take time to read this.

Of specific note, we carefully considered whether to raise the issue of prognostic uncertainty in the attached patient information sheet, and decided against it for two reasons:

1. We do not want to misrepresent a patient’s specific circumstances in what needs to be a generic project information sheet, and
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In the written information the patient had about the CARIAD project, we explained that the study was about “people nearing the end of their lives”. As such, at the time the clinical team approached the patient to take part in the CARIAD project, they believed that they fitted the study criteria (i.e. that the patient is likely in the last weeks of life). From the trial records, we note that the patient has survived longer than initially anticipated. This means that, due to project close-out, neither the patient nor the carer can participate in the project to the extent they initially expected and they will be withdrawn from the project.

They have been reassured that there will not be any effect on the care from the clinical team.

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