

# **Clinical effectiveness and cost-effectiveness results from the randomised, Phase IIB trial in previously untreated patients with chronic lymphocytic leukaemia to compare fludarabine, cyclophosphamide and rituximab with fludarabine, cyclophosphamide, mitoxantrone and low-dose rituximab: the Attenuated dose Rituximab with ChemoTherapy In Chronic lymphocytic leukaemia (ARCTIC) trial**

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## Plain English summary

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# Plain English summary

## What was the problem?

The first treatment that patients with chronic lymphocytic leukaemia (CLL) usually receive is a combination of the drugs fludarabine, cyclophosphamide and rituximab (Mabthera®, Roche Products Ltd) (FCR). However, research suggested that adding a fourth drug called mitoxantrone to FCR would improve response rates and that a lower dose of rituximab would work just as well as the standard dose.

## What did we do?

We established the Attenuated dose Rituximab with ChemoTherapy In CLL trial to compare fludarabine, cyclophosphamide, mitoxantrone and low-dose rituximab (FCM-miniR) with the standard FCR treatment. The trial recruited 200 participants.

## What did we find?

Three months after the end of treatment, participants were assessed to see how well they had responded. Part-way through the trial we looked at how half of the participants had responded and we found that participants who had received FCR had better response rates and fewer side effects than participants who had received FCM-miniR. The trial was, therefore, closed early and participants who were still receiving FCM-miniR were offered the chance to have FCR instead.

Follow-up assessments are ongoing but, to date, disease progression and overall survival data are good for all participants compared with previous studies.

## What does this mean?

The results of this trial show that FCR is a more effective treatment than FCM-miniR, and the addition of mitoxantrone to FCR increases side effects. FCR remains the best available therapy for CLL in patients who are considered fit for treatment with fludarabine.



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