Metformin in non-diabetic hyperglycaemia: the GLINT feasibility RCT

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Plain English summary

The GLINT feasibility RCT

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Plain English summary

Cardiovascular disease (CVD), such as a heart attack or a stroke, is the most common long-term condition in the UK. People with diabetes have an increased CVD risk. This risk is also increased in people with raised blood glucose levels who do not have diabetes, a condition referred to as non-diabetic hyperglycaemia (NDH).

Metformin is a cheap and effective diabetes treatment. In people with diabetes, metformin can reduce CVD risk and it may reduce the risk of cancer. It is unknown if metformin has this effect in people with NDH. We designed a trial of metformin (Glucophage® SR, Merck KGaA, Bedfont Cross, Middlesex, UK) compared with placebo in people with NDH to answer this question.

First, we evaluated whether or not such a trial was feasible. We tested if people with NDH were willing to take part. We assessed whether or not it was acceptable to post the study drug to participants' homes. We asked participants and their general practitioners (GPs) to complete health questionnaires to see if this data collection method worked. We also asked participants to provide blood samples.

We invited 5251 people to participate in the trial, recruited from general practices and research databases. Just under 10% of those contacted responded and 49% of those met the inclusion criteria. A total of 249 participants took part: 125 received metformin and 124 received an identical-looking placebo tablet.

Posting the study drug was acceptable; only a few packs needed to be replaced and people understood the instructions. The questionnaire return rates were high: 74% of participants and 79% of GPs returned the end-of-study questionnaire.

Most participants were able to take three tablets per day, but around 30% of participants in both the metformin group and the placebo group had stopped taking the study drug by 6 months. Both groups reported side effects, but more participants in the placebo group ranked these as very bothersome. Blood test results indicated that metformin was safe.

Around 20,000 people are needed for the full trial. This would require the use of large patient databases and changes to the trial design.

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