ISRCTN34091554 https://doi.org/10.1186/ISRCTN34091554

A double-blind, randomised, crossover study to investigate the difference in frequency of episodes of hypoglycaemia during treatment with Biphasic Insulin Aspart 30 (NovoMix®30) compared to Biphasic Human Insulin 30 (Mixtard® 30) in patients with well-controlled, type 2 diabetes

Submission date
07/06/2006

Recruitment status
No longer recruiting

Registration date
19/06/2006

Overall study status
Completed

Last Edited
19/02/2008

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Paul McNally

Contact details
Department of Diabetes and Endocrinology
Leicester Infirmary Close
Leicester
United Kingdom
LE1 5WW

Additional identifiers

Protocol serial number
BIAsp-1466

Study information

Scientific Title

Acronym
REACH

Study objectives
The trial is a double-blind, two-period cross-over, randomised, multicentre trial in insulin-treated subjects with type-2 diabetes comparing the efficacy and safety of NovoMix® 30 and Mixtard® 30.
Patients will first complete a screening and run-in period lasting eight weeks during which their current insulin dose will be adjusted to achieve pre-breakfast and pre-evening meal blood glucose levels of 5-7 mmol/l.
Patients who achieve an HbA1c of 6.5-8.5% at the end of the run-in period will be randomly allocated to treatment with either NovoMix® 30 or Mixtard® 30 for a 16-week treatment period. At the end of this period patients will be crossed over to the alternative treatment. The second crossover period will also last for 16 weeks. Both insulin regimens will involve administration just before meals. Total duration of the trial will be 40 weeks. Patients will self-check blood-glucose levels daily. Insulin total dosage will be adjusted by a maximum of either plus or minus 10% using the following algorithm in order to improve blood-glucose profiles, based on the targets stated above. The primary assessment variable will be the number of glucose readings below 3.5 mmol/l as measured by continuous glucose monitoring system overview (CGMS) during two 72-hour periods mid-way through and at the end of each treatment period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by South East Multicentre Research Ethics Committee (MREC) on 03/05/2002 reference number: MREC 01/1/67

Study design
Double-blind, randomised, crossover study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 2 diabetes requiring insulin

Interventions
Crossover trial comparing the glucose control of using NovoMix® 30 to Mixtard® 30.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Biphasic Insulin Aspart 30 (NovoMix® 30), Biphasic Human Insulin 30 (Mixtard® 30)

Primary outcome(s)
Frequency of hypoglycaemic episodes measured by CGMS for three days.

Key secondary outcome(s))
1. Frequency of reported severe hypoglycaemic episodes, minor hypoglycaemic events and nocturnal hypoglycaemia, during the last 12 weeks of each treatment period
2. HbA1c
3. Diabetes treatment satisfaction questionnaire
4. Adverse event recording

Completion date
07/11/2003

Eligibility

Key inclusion criteria
1. 160 male or female, adult subjects, with type 2 diabetes and treated with 1 - 3 injections of insulin daily for at least six months
2. HbA1c less than 9.5% at screening and 6.5 - 8.5 at randomisation
3. Judged by the investigator to be eligible for a twice a day (BID) mixed-insulin treatment regimen

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Impaired hepatic, renal or cardiac function
2. Concomitant oral hypoglycaemic agents
3. History of frequent severe hypoglycaemic episodes requiring external assistance within the last six months

Date of first enrolment
05/06/2002

Date of final enrolment
07/11/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Diabetes and Endocrinology
Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation
Novo Nordisk Ltd (UK)

ROR
https://ror.org/0415cr103

Funder(s)

Funder type
Industry

Funder Name
Novo Nordisk Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/05/2007		Yes	No