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Insulin Lispro mixtures (mid mixture and low mixture) administered three times daily compared with human insulin 30/70 administered twice daily in insulin-requiring patients with type 2 diabetes

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/02/2020	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Ian Gallen

Contact details
Diabetes Centre
Wycombe Hospital
Queen Alexander Rd
High Wycombe, Bucks
United Kingdom
HP11 2TT
+44 (0)1494 526161
abc@email.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0245131033

Study information

Scientific Title
Insulin Lispro mixtures (mid mixture and low mixture) administered three times daily compared with human insulin 30/70 administered twice daily in insulin-requiring patients with type 2 diabetes

Study objectives
To compare treatment with insulin lispro mid mixture (MM) before morning and midday meals and insulin lispro low mixture (LM) before the evening meal to treatment with human insulin 30 /70 twice daily with respect to haemoglobin A1C (HbA1c) levels in patients with type 2 diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised active controlled crossover group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Diabetes Type 2

Interventions
4 Weeks on 30/70 insulin bd then randomised to continue with 30/70 or start lispro mixes for 16 weeks. After 16 weeks crossover to comparator treatment.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Improvement in HbA1c levels
2. Improvement in home blood glucose measurements
3. Comparison of fructosamine
4. Comparison of doses
5. Comparison of hypoglycaemic episodes

Secondary outcome measures
Not provided at time of registration

Overall study start date
11/05/2000

Completion date
30/06/2002

Eligibility

Key inclusion criteria
Patients aged 35 years and over with type 2 diabetes and using insulin.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
11/05/2000

Date of final enrolment
30/06/2002

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Diabetes Centre
High Wycombe, Bucks
United Kingdom
HP11 2TT

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
South Buckinghamshire NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration