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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

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## Additional identifiers

**Protocol serial number**
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

### Study type(s)
Treatment

### 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(s)
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

### Key secondary outcome(s))
Not provided at time of registration

**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

**Healthy volunteers allowed**
No

**Age group**
Adult

**Sex**
All

**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**
United Kingdom

England

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

# Sponsor information

**Organisation**

Department of Health (UK)

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
South Buckinghamshire NHS Trust (UK)

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration