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Comparative study between two feeding schemes for glycaemic control in children with type 1 diabetes mellitus

Submission date	Recruitment status	[ ] Prospectively registered
25/06/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/01/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/01/2010	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
72/2008

Study information

Scientific Title
Comparative study of the effectiveness of two schemes dietetic glycaemic index of foods with high versus low postprandial glycaemic control in children with type 1 diabetes mellitus: a controlled cross-over clinical trial

Acronym
LGI, HGI

Study objectives
A dietetic scheme with a low glycaemic index (less than 55) will be more effective in maintaining the concentration of postprandial serum glucose (less than 180 mg/dl) than a dietetic scheme with a high glycaemic index in paediatric patients with diabetes mellitus type 1 (DM 1).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the National Institute of Pediatrics approved on the 2nd October 2008 (ref: 72/2008)

Study design
Crossover randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Type 1 diabetes mellitus

Interventions
Group 1 (n = 25): paediatric patients with diabetes mellitus 1 are fed with a dietetic scheme with a low glycaemic index low (less than 55)
Group 2 (n = 25): paediatric patients with diabetes mellitus 1 are fed with a dietetic scheme with a high glycaemic index (greater than 55)

Total duration of intervention: minimum 2 hours

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Concentration of post-prandial serum glucose
2. Type of dietetic scheme administered

Measured at 15, 30, 45, 60, 90 and 120 minutes.

Secondary outcome measures
Security settings:
1. Abdominal pain
2. Vomiting
3. Stool consistency
4. Temperature
5. Blood in stools
6. Fasting serum glucose
7. Ketones in urine

Measured at 15, 30, 45, 60, 90 and 120 minutes.

Overall study start date
01/06/2009

Completion date
30/06/2009

Eligibility

Key inclusion criteria
1. DM1 patients between 10 to 18 years of age monitored by the Department of Endocrinology, National Institute of Paediatrics
2. Patients of either sex
3. Patients with controlled DM1:
3.1. Concentration of fasting serum glucose 95 - 130 mg/dl
3.2. Glycosylated haemoglobin less than 7.5%
5. Signing of informed consent and settlement
6. Eight hours of fasting
7. Treated with intermediate and/or rapid long-acting insulin for more than 6 months

Participant type(s)
Patient

Age group
Child

Lower age limit
10 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Patients with infectious processes at least 72 hours of admission to the protocol
2. Patients with steroid treatment less than 24 hours prior to entry into the protocol
3. Patients who performed aerobic exercise greater than 30 minutes on the day prior to the start of this protocol
4. Elevated axillary temperature greater than 38°C at the start of the protocol (fever)

Date of first enrolment
01/06/2009

Date of final enrolment
30/06/2009

Locations

Countries of recruitment
Mexico

Study participating centre
Av. Coyoacan 1868 - 202
Mexico City
Mexico
03240

Sponsor information

Organisation
National Institute of Paediatrics (Instituto Nacional de Pediatria) (Mexico)

Sponsor details
Insurgentes Sur 3700 - C
Col. Insurgentes Cuicuilco
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Sponsor type
Government

Website
http://www.salud.gob.mx/unidades/pediatria/

ROR
https://ror.org/05adj5455

Funder(s)

Funder type
Government

Funder Name
National Institute of Paediatrics (Instituto Nacional de Pediatria) (Mexico)

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