

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

<b>Submission date</b> 25/06/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 04/01/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 04/01/2010	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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**  
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

## **Study type(s)**

Treatment

## **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(s)**

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

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

## **Key secondary outcome(s)**

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.

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Child

### **Lower age limit**

10 years

### **Upper age limit**

18 years

### **Sex**

All

### **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 Pediatría) (Mexico)

**ROR**

<https://ror.org/05adj5455>

## Funder(s)

**Funder type**

Government

**Funder Name**

National Institute of Paediatrics (Instituto Nacional de Pediatría) (Mexico)

## Results and Publications

Individual participant data (IPD) sharing plan

**IPD sharing plan summary**

Not provided at time of registration