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Intensive versus conventional insulin therapy for inpatient medical patients [Insulinoterapia intensificada versus terapia habitual en pacientes hospitalizados por patología médica]

Submission date
28/07/2009

Registration date
23/09/2009

Last Edited
23/09/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
SA08I20012

Study information

Scientific Title

Intensive versus conventional insulin therapy for inpatient medical patients: a single centre randomised open trial

Acronym
SUGAR-MINT

Study objectives
This trial will assess whether an adjustable insulin scheme which simulates the physiological secretion of this hormone is superior to standard treatment in medical inpatients with hyperglycaemia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Pontificia Universidad Católica de Chile (comité de ética de la Pontificia U. Católica de Chile) approved in December 2008

Primary study design
Interventional

Study design
Single centre randomised open trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hyperglycaemia

Interventions
The project is based in the Universidad Católica de Chile Hospital, which is the main private facility of the Pontificia Universidad Católica de Chile, in Santiago, Chile. The clinical team in charge of insulin therapy is composed by internists, hospitalists and nurses.

1. Group 1: Intensive insulin therapy with basal NPH and nutritional regular insulin. Consisting of:
1.1. Two doses of basal NPH insulin, standardised according to weight and insulin resistance
1.2. Regular insulin (short-acting) prior to meals ("nutritional") both in fixed dose and through a sliding scale

2. Group 2: Intensive insulin therapy with basal glargine and nutritional regular insulin. Consisting of:
2.1. One dose of basal glargine insulin, standardized according to weight and insulin resistance
2.2. Regular insulin (short-acting) prior to meals ("nutritional") both in fixed dose and through a sliding scale

3. Group 3: Standard Care. Consisting of regular insulin four times a day (qid) or NPH twice daily (bid), according to a sliding scale.

With the exception of insulin therapy, all other clinical decisions will be taken by the medical team in charge of the patient, which are independent from the research team. These include the administration of oral anti-diabetic drugs and the time of termination of insulin therapy.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Insulin

Primary outcome(s)
Number of measurements of blood glucose levels between 70 and 130 mg/dl. All measurements will be recorded at day 7 and at the moment of discharge.

Key secondary outcome(s)
1. Mean blood glucose level
2. Length of hospitalisation
3. Healthcare-associated infections
4. Number of measurements of blood glucose levels below 70 mg/dl
5. Time to achieve good glycaemic control (two or more measurements between 70 and 130 mg%)

All measurements will be recorded at day 7 and at the moment of discharge.

Completion date
01/06/2010

Eligibility

Key inclusion criteria
Adult inpatients (aged greater than 18 years, men and women) with an acute medical or surgical condition, and any of the following criteria:
1. In subjects known to have diabetes: Capillary blood glucose level over 180 mg/dl, in consecutive measurements separated by 2 hours, or just one measurement if insulin was administered after the first
2. In subjects without previous diagnosis of diabetes: Capillary blood glucose level over 200 mg /dl in consecutive measurements separated by 2 hours, or just one measurement if insulin was administered after the first

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Pregnancy
2. Acute complications of diabetes
3. Terminal illness (expected survival of less than a month)
4. Elective hospitalisation
5. Hospitalisation stay predicted to last less than 72 hours
6. Haemodyalisis initiated during hospitalisation
7. Peritoneal dialysis
8. Corticosteroids (prednisone) dose over 30 mg/day
9. Parenteral nutrition
10. Inability to receive carbohydrates by mouth for more than 8 hours
11. Patients with an unresolved surgical condition

Date of first enrolment
01/03/2009

Date of final enrolment
01/06/2010

Locations

Countries of recruitment
Chile

Study participating centre
Marcoleta 367
Santiago
Chile
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Sponsor information

Organisation
National Fund of Investigation and Development in Health (Fondo nacional de investigación y desarrollo en salud [FONIS]) (Chile)

Funder(s)

Funder type
Government

Funder Name
National Commission of Scientific Research and Technology, Ministry of Health (Chile) - Fifth National Contest of Projects of Investigation and Development in Health (FONIS 2008) (ref: SA08I20012)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration