

Metabolic control of hospitalized diabetes mellitus patients: Application of standardised insulin protocols to hospitalized diabetes mellitus patients

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
16/08/2007	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
03/09/2007	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
03/09/2007	Nutritional, Metabolic, Endocrine	<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

CIBH-1434

Study information

Scientific Title

Acronym

COMETADIH

Study objectives

Type 2 Diabetes Mellitus (DM2) is the leading cause of death and the most common diagnosis in hospitalized patients in Mexico. The economic burden that DM2 imposes to the public health system is onerous. Strategies focused on improving medical care and optimising resources are of paramount importance.

In-patient hyperglycemia negatively affects related comorbidities and has been linked to negative outcomes when compared to strategies that attain good glycemic control. Traditional insulin sliding scales are still widely used to treat in-patient hyperglycemia, even though this approach has been questioned and at present time is not considered good clinical practice. Novel strategies must be explored and compared to traditional insulin sliding scales.

Hypothesis of this study: Glycemic control of in-patients can be improved by the implementation of standardised insulin protocols. Glycemic control achieved by standardised insulin protocols will be better compared to traditional insulin sliding scales.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Human Biomedical Research Institutional Committee (an internal regulatory organisation for clinical research and ethics) approved this trial on June 10th, 2005 (ref: 1434).

Study design

Single-centre, interventional, randomized, unblinded trial.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Type 2 Diabetes Mellitus

Interventions

Two general wards of a tertiary care hospital were randomly assigned to one of two standardised insulin protocols.

The two protocols consist of different proportions of intermediate and regular unmodified human insulin. One of the protocols was delivered in 4 daily injections and the other in 3. At initiation total daily insulin dose was calculated with the same guidelines for both protocols,

further dose titration was provided according to pre-established glycemic goals and individual requirements.

Training was provided to the nursing and medical staff and adherence to the protocol guidelines was supervised by the research team.

After inclusion to this study the patient was treated with the protocol assigned to the ward. Capillary Blood Glucose (CBG) was measured 4 times a day. Fasting Venous Blood Glucose (VBG) was measured according to the attending physician decision. All hypoglycemic episodes were registered in one of two categories:

1. Laboratory hypoglycemia (CBG <60 mg/dL)
2. Clinical hypoglycemia (Presence of adrenergic or neuroglycopenic symptoms with CBG >60 mg /dL that reverted after the ingestion of food)

Cause of the hypoglycemic episode was tracked and registered.

The patient was followed until discharge or until transferred to other areas such as the intensive care unit.

Glycemic control was compared in both protocols and, in a secondary analysis, the best protocol was compared with historical controls.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

insulin

Primary outcome(s)

1. Mean CBG during study period
2. Mean VBG during study period
3. Hypoglycemic episodes

Key secondary outcome(s)

1. Clinical condition at the end of study period
2. Health team acceptance and adherence to the protocol guidelines
3. In-hospital morbidity and mortality registered during hospitalization

Completion date

30/05/2006

Eligibility

Key inclusion criteria

1. Adult hospitalized patients of any age or gender
2. Diabetes mellitus (World Health Organization criteria) and uncontrolled hyperglycemia on admission (capillary blood glucose >200 mg/dL or HbA1c >7.0)
3. Signed informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Good glycemic control on oral medication
2. Refusal to participate

Date of first enrolment

01/11/2005

Date of final enrolment

30/05/2006

Locations

Countries of recruitment

Mexico

Study participating centre

Direccion Medica

Mexico City

Mexico

14000

Sponsor information

Organisation

The National Institute of Medical Sciences and Nutrition (Mexico)

ROR

Funder(s)

Funder type

Other

Funder Name

This trial was funded by an unrestricted grant from institutional research budget of the National Institute of Medical Sciences and Nutrition (Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran). The National Institute of Medical Sciences and Nutrition is a non-profit organization, and its parental organizations are the Mexican Health Ministry (Secretaria de Salud de Mexico) and the Mexican National Autonomous University (Universidad Nacional Autonoma de Mexico). The National Institute of Medical Sciences and Nutrition is a tertiary care academic hospital.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration