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

Submission date 16/08/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 03/09/2007	**Overall study status** Completed	
Last Edited 03/09/2007	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Armando Villegas-Jimenez

Contact details
Direccion Medica
Vasco de Quiroga 15
Seccion XVI
Tlalpan
Mexico City
Mexico
14000
+52 55 56 55 90 68
armandov@quetzal.innsz.mx

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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-stablished glycemic goals and individual requirements.

Training was provieded 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 transfered 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 measure
1. Mean CBG during study period
2. Mean VBG during study period
3. Hypoglycemic episodes

Secondary outcome measures

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

Overall study start date
01/11/2005

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

Age group
Adult

Sex
Both

Target number of participants
Forty five patients on each protocol. Al teast ninety patients overall.

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)

Sponsor details
Vasco de Quiroga 15
Seccion XVI
Tlalpan
Mexico City
Mexico
14000
+52 55 54 87 09 00
acabral@quetzal.innsz.mx

Sponsor type
University/education

Website
http://www.innsz.mx

ROR
https://ror.org/00xgvev73

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

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