

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

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<b>Registration date</b> 03/09/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 03/09/2007	<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

### Contact name

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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