

Evaluation of an algorithm for intensive subcutaneous insulin therapy in emergency room patients with hyperglycaemia

Submission date 17/07/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 17/08/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/04/2019	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00353431

Protocol serial number
EKBB13/06

Study information

Scientific Title

Evaluation of an algorithm for intensive subcutaneous insulin therapy in emergency room patients with hyperglycaemia

Acronym

Euglycemia

Study objectives

Time in the glycaemic target range (5.5 to 7.0 mmol/l) during the period of observation of 48 hours expected to be longer in the intensive insulin group.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local Ethics Committee of Basel, Switzerland (EKBB) approval, 20/03/2006, ref: 13/06

Study design

Interventional randomised open-label active-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

All medical patients with a plasma glucose concentration more than 8 mmol/l

Interventions

Comparison of a normal sliding scale with subcutaneous (s.c.) insulin injections versus the new algorithm with s.c. insulin injections (in both groups NovoRapid ®)

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Subcutaneous insulin

Primary outcome(s)

Time in the glycaemic target range (5.5 to 7.0 mmol/l) during the period of observation of 48 hours (expected to be longer in the intensive insulin group).

Key secondary outcome(s)

1. Time to reach the target range (expected to be shorter in the intensive insulin group)
2. Frequency of hypoglycaemia (plasma glucose less than 3.8 mmol/l) (safety endpoint, expected

to be similar in the two groups)

3. Frequency of severe hypoglycaemia (plasma glucose less than 2.5 mmol/l) (safety endpoint, expected to be similar in the two groups)

4. Frequency of hypokalaemia (safety endpoint, expected to be similar in the two groups)

Completion date

30/04/2008

Eligibility

Key inclusion criteria

1. All patients with hyperglycaemia (more than 8.0 mmol/l) admitted to the medical emergency room
2. Patients with presumed hospitalisation in the Emergency Room (ER) or medical ward of more than 48 hours duration

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Total final enrolment

130

Key exclusion criteria

1. Patients in shock (defined as hypotension or shock index more than one with oliguria, changed mental status and metabolic acidosis)
2. Patients with a terminal illness on palliative care
3. Patients with type one diabetes
4. Patients with insulin pump therapy
5. Patients with need for hospitalisation in the intensive or coronary care unit
6. Patients with presumed hospitalisation shorter than 48 hours
7. Known pregnancy (in women of birthbearing age pregnancy test for exclusion mandatory)
8. No informed consent

Date of first enrolment

31/08/2006

Date of final enrolment

30/04/2008

Locations

Countries of recruitment

Switzerland

Study participating centre

Petersgraben 4

Basel

Switzerland

4031

Sponsor information

Organisation

University Hospital of Basel (Switzerland)

ROR

<https://ror.org/04k51q396>

Funder(s)

Funder type

Industry

Funder Name

Novo Nordisk (Switzerland)

Alternative Name(s)

Novo Nordisk Global

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

Denmark

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/06/2013	16/04/2019	Yes	No
Basic results				No	No