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

Submission date
17/07/2006

Registration date
17/08/2006

Last Edited
16/04/2019

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00353431

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 versuss 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 measure
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).

Secondary outcome measures
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)

Overall study start date
31/08/2006

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

Age group
Not Specified

Sex
Both

Target number of participants
140

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)

Sponsor details
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Sponsor type
University/education

Website
http://www.endo-diabasel.ch

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

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

Study outputs

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