Stress ulcer prophylaxis with proton pump inhibitor (pantoprazole) in adult critically ill patients in the intensive care unit: A randomized, blinded, placebocontrolled trial

Published: 26-10-2015
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To assess the benefits and harms of SUP with PPI in adult, critically ill patients in the ICU.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal vascular conditions
Study type	Interventional

Summary

ID

NL-OMON42819

Source
ToetsingOnline

Brief title
SUP-ICU trial

Condition

- Gastrointestinal vascular conditions
- Respiratory tract infections

Synonym
stomach ulcer, stress ulcer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Innovation Fund Denmark (4108-00011A).

Intervention

Keyword: Stress ulcer prophylaxis

Outcome measures

Primary outcome

Primary outcome: Mortality 90 days after randomization.

Secondary outcome

Secondary outcomes: proportion of patients with clinically important GI bleeding, pneumonia, Clostridium difficile infection and myocardial ischemia, proportion of patients with clinically important GI bleeding, proportion of patients with pneumonia or clostridium difficile infections, 1 year mortality post-randomization, days alive without organ support in the 90-day period, serious adverse reactions and a health economic analysis.

Study description

Background summary

Critically ill patients in the intensive care unit (ICU) are at risk of stress related gastrointestinal (GI) bleeding, and stress ulcer prophylaxis (SUP) is recommended. However, the evidence on SUP is of low quantity and quality, and studies have shown that proton pump inhibitors (PPI) may increase the risk of a number of serious adverse events.

Study objective

To assess the benefits and harms of SUP with PPI in adult, critically ill patients in the ICU.

Study design

An investigator-initiated, pragmatic, international, multicentre, randomized, blinded, parallel-group trial of SUP with PPI versus placebo.

Intervention

Experimental intervention is intravenous pantoprazole 40 mg daily. Control intervention is matching placebo (saline).

Study burden and risks

Since PPI is a well-established drug and thousands of patients are treated with it every day, there will be no additional risk to patients receiving PPI. The risk will be limited to the known adverse effects, including intolerance, abdominal pain and headache (appendix 2)
From the available evidence we do not know whether there will be a higher risk of GI bleeding, pneumonia, CDI, cardiovascular events or mortality in the PPI or placebo groups [31].

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adult patients admitted to the ICU with one or more of the following acute conditions: shock, renal replacement therapy, mechanical ventilation expected to last > 24 hours, any kind of coagulopathy, treatment with anticoagulant drugs or liver disease.

Exclusion criteria

contraindications to PPI, daily treatment with PPI and/or histamine-2-receptor antagonist, GI bleeding of any origin or known peptic ulcer during current hospital admission, organ transplant, withdrawal from active therapy or brain death, positive urine human chorionic gonadotropin (hCG) or plasma hCG or consent according to national regulations not obtainable

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-07-2016

Enrollment:	100
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	pantoprazole
Generic name:	pantoprazole
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	26-10-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	02-02-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-03-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-07-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-11-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2015-000318-24-NL
ClinicalTrials.gov	NCT02467621
CCMO	NL54425.042.15