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Factor XIII in patients with alcohol abuse disorder

Submission date	Recruitment status	[ ] Prospectively registered
10/12/2008	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/12/2009	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/09/2015	Mental and Behavioural Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Claudia Spies

Contact details
Chariteplatz 1
Berlin
Germany
10117
+49 (0)30 450 55 10 01
claudia.spies@charite.de

Additional identifiers

Study information

Scientific Title
Can the infusion of factor XIII shorten the length of hospital stay in patients with chronic alcohol use disorder? A prospective, randomised, placebo-controlled trial

Acronym
Factor XIII

Study objectives

1. Chronic alcohol use leads to a variation of the pre- and post-operative plasma concentration of factor XIII
2. The application of factor XIII results in lower bleeding complications after surgery, less infections and impaired wound healing
3. Factor XIII can shorten the hospital stay in patients with chronic alcohol use disorder

On 28/09/2015 the target number of participants was changed from 40 to 80.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Charité - University Medicine Berlin, 08/07/2004

Primary study design
Interventional

Study design
Prospective randomised placebo-controlled double-blinded two-arm single-centre trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic alcohol use disorder

Interventions
There are five drug administration points, the duration of infusion takes about 20 minutes:
1. Pre-operative 2500 IE intravenous (i.v.) fibrogammin or placebo (NaCL 0.9% Lsg.)
2. Post-operative 1250 IE i.v. fibrogammin or placebo
3. First day post-operative 1250 IE i.v. fibrogammin or placebo
4. Second day post-operative 1250 IE i.v. fibrogammin or placebo
5. Third day post-operative 1250 IE i.v. fibrogammin or placebo

Blood samples are taken 2 x pre-operatively (1 x before and after fibrogammin) and 1 x post-operatively and on the 1, 4, and 10 day post-operative; clinical evaluation of the patient (bleeding /wound/complications) every day.

Please note that as of 22/10/2010 the status of this trial has been updated to "Completed". The end date of this trial was recorded as 18/01/2010. The originally anticipated end date was 20/10 /2010.

Please note that as of 28/09/2015 the status of this trial has been updated to “Stopped”: recruiting participants has halted prematurely and will not resume due to futility; participants are no longer being examined or treated.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Factor XIII

Primary outcome(s)
Modified factor XIII levels in peripherial blood samples and immune suppression, examined at six measure points during hospital stay.

Key secondary outcome(s)
1. Evaluation of peri-operative coagulation function and status - at six measure points during the hospital stay
2. Peri-operative incidence of bleeding complications and impaired wound healing, examined the whole time during hospital stay of the patient
3. Length of hospital stay

Completion date
18/01/2010

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
Current inclusion criteria as of 28/09/2015:
1. Aged greater than or equal to 18 years, either sex
2. Written informed consent of the patient
3. 40 patients without daily alcohol consumption and 40 patients with alcohol consumption more or equal to 60 g per day
4. Patients undergoing elective tumour resection in oropharyngeal region and elective orthopedic surgery

Previous inclusion criteria:
1. Aged greater than or equal to 18 years, either sex
2. Written informed consent of the patient
3. Alcohol consumption more or equal to 60 g per day
4. Patients undergoing elective tumour resection in oropharyngeal region

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex

All

Key exclusion criteria
1. Age under 18 years
2. No wiritten consent from patient
3. Liver cirrhosis (stage Child B or C)
4. Congenital or acquired coagulation disorders
5. Terminal renal insufficiency
6. Angina pectoris or congestive heart failure
7. Immune suppression
8. History of pulmonary embolism or deep venous thrombosis

Added 28/09/2015:
9. Therapy with Anticoagulant of Vitamin-K-Antagonist-Type

Date of first enrolment
29/08/2007

Date of final enrolment
18/01/2010

Locations

Countries of recruitment
Germany

Study participating centre
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin)
Berlin
Germany
10117

Sponsor information

Organisation
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
Charité Universitätsmedizin Berlin

Alternative Name(s)
Medical School - Charité - University Medicine Berlin

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration