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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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N/A

## 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

## Study design
Prospective randomised placebo-controlled double-blinded two-arm single-centre 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
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 measure
Modified factor XIII levels in peripherial blood samples and immune suppression, examined at six measure points during hospital stay.

### Secondary outcome measures
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

### Overall study start date
20/10/2005

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
80

### 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)

**Sponsor details**
Chariteplatz 1
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10117
-
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**Sponsor type**
Hospital/treatment centre

**Website**
http://www.charite.de/

**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

**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