ISRCTN10353850 https://doi.org/10.1186/ISRCTN10353850

Use of preoperative desmopressin in preventing bleeding in patients treated with selective serotonin reuptake inhibitors (SSRIs)

Submission date 20/12/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 02/09/2008	**Condition category** Surgery	

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
UMCU 04-298; NTR175

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised, double-blinded, placebo controlled, parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Primary haemostasis disorder

Interventions
Pre-operative infusion placebo/desmopressin:
1. Less than 50 kg: 15 µg
2. 50 - 100 kg: 30 µg
3. Greater than 100 kg: 45 µg

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Desmopressin

Primary outcome measure

Pre- and post-operative blood loss.

Secondary outcome measures
1. Peri- and post-operative haemoglobin
2. Number of peri-operative blood transfusion
3. Peri-operative fluid infusion
4. Post-operative drainage

Overall study start date
01/01/2005

Completion date
01/06/2007

Eligibility

Key inclusion criteria
1. Patients aged over 18 who receive a serotonergic antidepressant (fluvoxamine, fluoxetine, paroxetine, sertraline, venlafaxine, clomipramine, citalopram) at least started two weeks before the surgery
2. Surgery: orthopedic, abdominal, breast

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
300. Patients have been recruited since 07/04/05.

Key exclusion criteria
1. No informed consent
2. Disorder in primary haemostasis
3. Hyponatraemia (sodium [serum] less than 130 mmol/l)
4. Laparoscopic surgery
5. Use of vitamin K antagonists, aspirin, iron supplements, methotrexate, heparin
6. Acute coronary syndrome (unstable angina and myocardial infarction)
7. Spinal anaesthesia during surgery

Date of first enrolment
01/01/2005

Date of final enrolment

01/06/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Willy Brandtlaan 10
Ede
Netherlands
6716 RP

Sponsor information

Organisation
Hospital Gelderse Vallei (The Netherlands)

Sponsor details
P.O. Box 9025
Ede
Netherlands
6710 HN

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03862t386

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hospital Gelderse Vallei (The Netherlands)

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