

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
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 02/09/2008	Condition category Surgery	☐ Individual participant data ☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

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

Study type(s)

Not Specified

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(s)

Pre- and post-operative blood loss.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

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)

ROR

<https://ror.org/03862t386>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Hospital Gelderse Vallei (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration