Same day mobilisation after TF-AVI procedure (MobiTAVI)?

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21755

Source
NTR

Brief title
MobiTAVI

Health condition

Patients with severe aortic stenosis (eligible for invasive treatment which are not suitable for conventional surgical aortic valve replacement and thus eligible for T(F)AVI.)

Sponsors and support

Primary sponsor: Academical medical centre of Amsterdam

Intervention

Outcome measures

Primary outcome

- Vascular and bleedingcomplications

- Pain and patient comfort

Secondary outcome

- Infection rate

- Need for, and time of, CAD in situ

- Quality of life (SF-36 and EQ-5D questionnaire)

- Hospitalisation stay duration

- Delirium

Study description

Background summary

In this study we assess if it is save and better to mobilize TF-AVI patients early (4-6 hours) after the procedure. Our hypotheses is that this can be done safely and with better patient comfort, less pain complaints and lower complication rates associated with the elderly patient during hospital stay (infections, deliria).

Study objective

Early mobilisation, i.e. 6 hours after vascular closure after TF-AVI procedure, will maximize comfort, lower pain complaints, lower infection rate and raise overall patient wellbeing after TAVI-procedure without extreme increase in vascular complications (i.e. access site bleedings/hematomas)

Intervention

Either, after primary and secondary survey, early mobilisation (4-6 hours after procedure) either immobilisation according to protocol until the next morning, depending on planning of procedures during the day.

Contacts

Public
Meibergdreef 9 (Academical Medical Centre Amsterdam)

Jeroen Vendrik
Room TKs0-248

Amsterdam 1105 AZ

The Netherlands
+31 (0)20 566 5204 / +316 46032024
Scientific
Meibergdreef 9 (Academical Medical Centre Amsterdam)

Jeroen Vendrik
Room TKs0-248

Amsterdam 1105 AZ
The Netherlands
+31 (0)20 566 5204 / +316 46032024

Eligibility criteria

Inclusion criteria

- All TF-AVI patients at the AMC

Exclusion criteria

- Pre-existent problems with mobility (i.e. wheelchair indepency, inability to transfer)

- Pre-TAVI INR>2,0

- Heparine-infusor after TAVI-procedure

- Need for vascular closure by (vascular) surgeon at catheterisation room

- Operator’s opinion (difficult access site closure; >20 minutes manual pressure needed before hemostasis is reached)

- Temporary pacemaker placement

- Contra-indications at secondary assessment (+4 hrs after procedure)

o Symptomatic hypotension

o Active bleeding

o Hematoma (> 5cm diameter)

o Rhythm or conduction disorders on ECG

o Extreme pain at access site

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-10-2016
Enrollment:	0
Type:	Unknown

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL5910
NTR-old	NTR6098
Other	: AMCW16_289

Study results