-Study on the effect of the interaction of short-term combined use of NSAIDS with diuretics and/or RAAS-inhibitor in post-operative elective orthopedic patients

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to study the effect of short term combined use of NSAIDS with diuretics/RAAS-inhibitors on the heart and kidneyfunction in orthopedic patients undergowing a knee- or hip-replacement

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON31513

Source
ToetsingOnline

Brief title
KNION-study

Condition

- Heart failures
- Joint disorders
- Renal disorders (excl nephropathies)

Synonym
heart failure, hypertension

Research involving
Human

Sponsors and support

Primary sponsor: Deventer Ziekenhuis
Source(s) of monetary or material Support: ziekenhuisbudget in kader van opleiding

Intervention

Keyword: diuretics, NSAID, RAAS-inhibitors, short-term interactions

Outcome measures

Primary outcome

- systolic bloodpressure

- diastolic bloodpressure

- glomulair filtration rate

Secondary outcome

- oedema

- serum creatinine

- serum Na+

- serum K+

- consult cardiology/internal

- dose reduction/escalation diuretics/RAAS-inhibitor

Study description

Background summary

a clinical relevant interaction is know between diuretics/RAAS-inhibitors use of NSAIDS. Only of the long-term use of this combination has the clinical relevance been esthablished.

In patients undergowing knee- or hip-replacement surgery NSAIDS are used to prevent heterotopic ossification, also in this combination

Study objective

to study the effect of short term combined use of NSAIDS with diuretics/RAAS-inhibitors on the heart and kidneyfunction in orthopedic patients undergowing a knee- or hip-replacement

Study design

prospective, controlled, clinical observational study

Study burden and risks

during clinical admission;
- extra bloodpressure measurements
- extra oedema measurements
- extra bloodsample (one)

takeing a bloodsample kan be painful and can possibly cause bruiseing

Contacts

Public
Deventer Ziekenhuis

Ceintuurbaan 4a
7415HL
Nederland
Scientific
Deventer Ziekenhuis

Ceintuurbaan 4a
7415HL
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

elective knee- or hipreplacement
use of RAAS-inhibitors and diuretics

Exclusion criteria

hipfracture with replacement
revision of the knee or hip
hospitalisation <4 days
nephrotoxic drugs
other medication use with possible NSAID's interactions

Study design

Design

Study phase:	4
Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2008
Enrollment:	124

Type:	Actual

Ethics review

Approved WMO Date:	19-05-2008
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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
CCMO	NL17822.075.07