

-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 undergoing 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 can 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

CCMO

ID

NL17822.075.07