Non Steroidal Anti-Inflammatory Drugs and the antiplatelet effects of acetylsalicylic acid.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27645

Source
NTR

Brief title
NSAID's and ASA research

Health condition

Acetylsalicylic acid
NSAIDs
Antiplatelet

Acetylsalicylzuur
NSAIDs
Antitrombotisch

Sponsors and support

Primary sponsor: H.E. Vonkeman, M.D., Ph.D., rheumatologist, epidemiologist: is the performer of the trial
Source(s) of monetary or material Support: H.E. Vonkeman, M.D., Ph.D., rheumatologist, epidemiologist: is the performer of the trial.

Intervention

Outcome measures

Primary outcome

To measure the pharmacodynamic interaction between naproxen + acetylsalicylic acid as compared to the placebo + acetylsalicylic interaction. Also the pharmacodynamic interaction between acetylsalicylic acid and other in The Netherlands often used NSAID's will be examined: ibuprofen, meloxicam and etorixocib (also compared to placebo + acetylsalicylic acid).

The main study parameter is the difference in closure time (sec) as a measure of platelet aggregation. Closure time is measured by the Platelet Function Analyzer-100 (PFA-100). This apparatus measures the time needed for the blood to aggregate.
The difference calculated, is closure time of the addition of an NSAID to acetylsalicylic acid, versus closure time of acetylsalicylic acid and placebo within one subject.

Secondary outcome

N/A

Study description

Background summary

While concern exists about the safety of the interaction between acetylsalicylic acid (prophylactic use) and NSAID's, observational research and intervention studies give conflicting results about this interaction. Because of the relatively safety of naproxen in cardiovascular disease compared to diclofenac it is interesting to look at the pharmacodynamic interaction between naproxen and ascetylsalicylic acid, to be able to advise about what is the best combination in a case the combination of acetylsalicylic acid and a NSAID is needed. Also there is a need to more closely look at this interaction with ibuprofen, meloxicam and etoricoxib, all often used in The Netherlands.

Study objective

While prophylactic use of acetylsalicylic acid and Non Steroidal Anti-Inflammatory Drugs (NSAID’s) is often used concomitantly for long periods of time, there is concern about the safety of this combination in preventing cardiovascular disease. There is still a debate about the inhibitory effect of NSAID’s on the cardio protective effect of acetylsalicylic acid.

There is conflict in results of observational research, where combination of ibuprofen and

acetylsalicylic acid increased, or decreased the cardiovascular risk compared to acetylsalicylic acid alone, and a pharmacodynamic study where ibuprofen inhibited the effect of acetylsalicylic acid, taken 12 hours before the acetylsalicylic dose. Based on this study, pharmacists advise to give diclofenac instead of ibuprofen in combination with acetylsalicylic acid. However, in meta-analysis on the overall risk of cardiovascular disease, diclofenac seems to be relatively harmful while naproxen tends to be relatively save. Pharmacodynamic research to the interaction between naproxen and acetylsalicylic acid, shows only a just significant inhibitory effect of naproxen on the platelet-aggregation-inhibitory effect of acetylsalicylic acid, while naproxen itself gave a strong blood-platelet-aggregation-inhibitory effect.
This is a decisive study on the potential naproxen + acetylsalicylic acid interaction.

Study design

For each volunteer, the study consists of 3 cycles of 3 days during which 3 or 4 doses of study medication (2 or 3 x NSAID and 1 x acetylsalicylic acid) will be taken, and 2 medication-free wash out periods of 12 days. Total duration of the study for one volunteer is 33 days. Volunteers are randomised in one of two groups.

Intervention

Subjects will receive 2 doses of etoricoxib 90 mg and meloxicam 15 mg, or 3 doses of naproxen 500 mg and ibuprofen 600 mg, mg (one NSAID per cycle). Subjects will also receive three times one dose of acetylsalicylic acid 80 mg (one during each cycle). As a comparator subjects will receive 3 times one placebo tablet (during one of the three cycles).

Contacts

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Eligibility criteria

Inclusion criteria

Healthy volunteers.

Exclusion criteria

1. Use of medicins of any kind (also alternative medicins) except for oral contraceptives;

2. Allergy to acetylsalicylic acid and / or NSAID’s;

3. History of stomach ulcer(s) or stomach bleeding;

4. History of stroke;

5. Cardiovascular disease;

6. Renal insufficiency;

7. Thrombocytose;

8. Thrombopenia;

9. Aenemia;

10. Von Willebrand’s disease;

11. Pregnancy, or or current pregnancy wish.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	09-01-2009
Enrollment:	30
Type:	Anticipated

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	NL1830
NTR-old	NTR1940
Other	METC Medisch Spectrum Enschede : P09-01
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A