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

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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....

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27645

Bron
NTR

Verkorte titel
NSAID's and ASA research

Aandoening

Acetylsalicylic acid
NSAIDs
Antiplatelet

Acetylsalicylzuur
NSAIDs
Antitrombotisch

Ondersteuning

Primaire sponsor: H.E. Vonkeman, M.D., Ph.D., rheumatologist, epidemiologist: is the performer of the trial
Overige ondersteuning: H.E. Vonkeman, M.D., Ph.D., rheumatologist, epidemiologist: is the performer of the trial.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Healthy volunteers.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd

Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	09-01-2009
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1830
NTR-old	NTR1940
Ander register	METC Medisch Spectrum Enschede : P09-01
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A