Influence of the use of indometacin on reaction time, postural balance and obstacle avoidance in healthy adolescent subjects.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON30755

Source
ToetsingOnline

Brief title
Indometacin and risk of falling.

Condition

- Other condition

Synonym
free of diseases, healthy

Health condition

gezonde proefpersonen

Research involving

Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: SMK

Intervention

Keyword: indometacin, obstacle avoidance, postural balance, reaction time

Outcome measures

Primary outcome

Successrate on the obstacle avoidance task.

Secondary outcome

Reactiontime

Root Mean Square (RMS) of the velocity and amplitude of the Centre of Pressure

(COP)

Study description

Background summary

A lot of (epidemiologic) research is done on causes for falls and factors contributing to falling. Most of this research was conducted on elderly, either community-dwelling or institutionalised. It became clear that elderly have a greater risk at falling because of:
- physiological changes due to increasing age [Gerdhem et al., 2005]
- previous falls [Myers et al., 1991; Lipsitz et al., 1992]
- comorbidity (including RA) [Bergland et al., 2004; Gerdhem et al., 2005; Lawlor et al., 2003]
- polypharmacy [Lawlor et al., 2003; Walker et al., 2005; Ziere et al., 2005]
and/or
- use of specific drugs like antidepressives, benzodiazepines, vasodilatators and NSAIDs [Cumming R, 1998; Herings RMC, 2001; Kallin K et al., 2004; Granek et al., 1987].
The relation between benzodiazepines and falling has been extensively investigated in and affirmed by several fields of research and is practically

common sense. However, the (possible) relation between NSAIDs and falling is much less investigated, even though there are various articles in which a higher risk of falling when using NSAIDs is stated; sometimes the risk is even as high as with benzodiazepines [Cumming R, 1998; Granek et al., 1987; Walker et al., 2005].

Study objective

NSAIDs are drugs that are often prescribed to patients with rheumatic or orthopedic diseases. They seem to be at a greater risk for falls than healthy persons because of their disease, age and medication use. Therefore it is very important to keep this risk as small as possible. In this study healthy adults are measured on reactiontime, postural balance and obstacle avoidance with and without a single dose of indometacine or placebo. This is done in order to gain more comprehension in the mechanism and actual risk for falls when using NSAIDs.

Study design

Doubleblind placebo-controlled cross-over design.

Study burden and risks

The subjects will be measured four times for 3 hours and it will not bring them any benefits. There is a minimal risk for side effects (especially gastro-intestinal problems) of indometacin. Provided that these side effects will occur anyway, they will last for a short time and will be treated adequately by the investigator. The risk for injuries caused by the tasks is minimal as well; falls will be prevented by means of a safety harness or handrails.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- age between 50-70
- not using any NSAIDs for at least 3 days prior to the test session

Exclusion criteria

- neurological or orthopedic disorders
- poor comprehension of Dutch language
- hearing problems
- severe problems with heart and/or bloodvessels
- acutely existing Ulcus ventriculi and/or duodeni, or history of Ulcus
- allergy against Indomethacin, Aspirin, or other NSAIDs
- patients with nasal polyps reacting with an angioedema to other NSAIDS
- severe preexisting renal and liver damage
- comedication
- over 100kg of weight

Study design

Design

Study phase: 4

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	indocid
Generic name:	indometacin
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	13-04-2007
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
EudraCT	EUCTR2006-005324-17-NL
CCMO	NL14489.091.06