Effects of paracetamol use on the immune response after hepatitis B vaccination

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Study the association between timing of the use of paracetamol during hepatitis B vaccination and the development of an antibody response in health care students who are routinely vaccinated with hepatitis B vaccine.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON36173

Source
ToetsingOnline

Brief title
Paracetamol and hepatitis B vaccination

Condition

- Other condition

Synonym
er wordt geen aandoening bestudeerd, nvt

Health condition

vaccinatierespons

Research involving
Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: strategisch onderzoek RIVM

Intervention

Keyword: antibody titers, hepatitis B, immune response, paracetamol

Outcome measures

Primary outcome

Antibody concentrations prior to and 1 month after the third vaccination

(booster vaccination) will be measured. Antibody concentrations expected to be

lower in participants that used paracetamol prophylactically. The titers in

the groups treated therapeutically with paracetamol cannot be predicted and

are subject of this study.

Secondary outcome

Alterations in the functionality of specific lymfocyte subpopulations in blood

of participants that used paracetamol prophylactically.

Study description

Background summary

Paracetamol (Acetaminophen) is an over the counter medicine and considered safe when used according to the instruction leaflet. The 'consultatiebureau' advices to use paracetamol as a remedy for pain and fever after vaccination in small children. Children or adults who have experienced fever or pain after vaccination are advised to use paracetamol prior to further vaccinations. Recently published results indicates a negative influence on vaccination response (lower antibody titers) in infants that were prophylactically administered paracetamol prior to vaccination to prevent fever. It is not known if there is an important role for timing of paracetamol in this effect on vaccination response and if paracetamol also has this effect when used therapeutically. It is important to gain insight into the effects of

paracetamol use during vaccination. Health organisations should have enough information to offer a good advice about the use of paracetamol during vaccination procedures.

Study objective

Study the association between timing of the use of paracetamol during hepatitis B vaccination and the development of an antibody response in health care students who are routinely vaccinated with hepatitis B vaccine.

Study design

The first month of the study is interventional, after that it will turn into an observational study.

Intervention

There are three invervention groups that have to take paracertamol for 24 hours (1000 mg / 8h). Timing of the paracetamol use is different: group 1 will take paracetamol at the time of vaccination (prophylactic use), group 2 starts taking paracetamol 6 hours after vaccination (therapeutic use 1), and group 3 starts taking paracetamol 24 hours after vacciantion (therapeutic use 2). There is a control group that takes no paracetamol. Every participant will take paracetamol according to one of the four groups during the first and second hepatitis B vaccinations.

Study burden and risks

Participants who take paracetamol prophylactically or therapeutically will probably suffer less from side effects of vaccination, such as fever and pain. Participation to this study will significantly contribute to the scientific knowledge, resulting in a better advice of health organizations about the use of paracetamol during vaccination procedures.
There is a possibility that some participants could have a reduced antibody titer at the end of the study. The antibody concentration of every participant will be determined and evaluated, like is routinely done after hepatitis B vaccination. An extra booster vaccination will be offered if the antibody concentration is too low for protection against hepatitis B. This is the normal policy and is not different for students that participate in this study and those that do not.
The study population exists of young health care students that are routinely vaccinated against hepatitis B. In the vaccination protocol a blood sample is routinely taken 1 month after the third vaccination and for this study we will draw 14 mL. of extra blood. An extra blood sample (14 ml.) will be taken specifically for this study prior to the third vaccination. Antibody titers

and functionality of lymphocyte subpopulations will be determined in the blood.

Contacts

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RIVM

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Good health.
- Able to perform the study according to the procedures.
- Informed consent present.

Exclusion criteria

- History of acute or chronic hepatitis B
- Earlier hepatitis B vaccination
- Evidence of a serious disease, that needs immunosuppresive treatment.
- A known primary or secondary immunodeficiency

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	276
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Engerix-B
Product type:	Medicine
Brand name:	Paracetamol
Generic name:	Paracetamol
Registration:	Yes - NL intended use

Ethics review

Not approved

Date:	22-03-2011

Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	14-04-2011
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2011-000923-33-NL
CCMO	NL35901.000.11