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

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Phase 1: Investigate a possible suppressing effect of prophylactic paracetamol use in adults on the response of the hepatitis B vaccination. Phase 2: Study the association between timing of the use of paracetamol during hepatitis B vaccination and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38027

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

Phase 1: Antibody concentrations prior to and 1 month after the third vaccination (booster vaccination) will be measured. Antibody concentrations expected to be 65% lower in participants that used paracetamol prophylactically. This expectation is based on findings in baby's (Prymula et al., 2009).

Phase 2: Antibody concentrations prior to and 1 month after the third vaccination (booster vaccination) will be measured.
It is expected that the titers in the groups treated therapeutically with paracetamol will be inbetween the control and prophylactically treated group.

Secondary outcome

Alterations in the functionality of specific lymfocyte subpopulations in blood (1 month after the third vaccination) 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. Individuals 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. A lower vaccination response could result in lower effectivity of vaccination. This effect has not been shown in adults to date. Also, it is not known if there is an important role for timing of paracetamol - prophylactic or therapeutic use - in this effect on vaccination response. 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

Phase 1: Investigate a possible suppressing effect of prophylactic paracetamol use in adults on the response of the hepatitis B vaccination.
Phase 2: Study the association between timing of the use of paracetamol during hepatitis B vaccination and the development of the immune response in adults.

Study design

Two-phase study. In phase 1 we will investigate if prophylactic use of paracetamol has an effect on the immune response of adults after a hepatitis B vaccination. In phase 2 we will investigate if there is a difference between prophylactic and therapeutic use of paracetamol on the vaccination response. The first month of phase 1 and 2 of the study is interventional, after that it will turn into an observational study.
It is important to realize that we only start with phase 2 of this study if we find any effects of paracetamol on the immune response after vaccination in phase 1.

Intervention

Phase 1: There is one intervention and one control group. The intervention group have to take paracertamol for 24 hours (1000 mg / 8h) starting directly after the vaccination. The control group takes no paracetamol. Every participant will take paracetamol according to the intervention or control group during the first and second hepatitis B vaccinations.

Phase 2: There are two 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) and group 2 starts
taking paracetamol 6 hours after vaccination (therapeutic use 1). Every participant will take paracetamol according to one of the three 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 21
mL. of extra blood. An extra blood sample (7 ml.) will be taken specifically for this study prior to the third vaccination.
Antibody titers (prior to and 1 month after the third vaccination) and functionality of lymphocyte subpopulations (1 month after the third vaccination) will be determined in the blood.

Contacts

Public
RIVM

Antonie van Leeuwenhoeklaan 9-11
Bilthoven 3720 BA
NL
Scientific
RIVM

Antonie van Leeuwenhoeklaan 9-11
Bilthoven 3720 BA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
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: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-08-2011
Enrollment:	489
Type:	Actual

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

Approved WMO Date:	28-04-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-07-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	30-07-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-08-2012
Application type:	Amendment

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL36577.041.11