Tetanus prophylaxis.

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Using vaccination history as a representative for a persons immune status leads to overprescription of tetanus toxoid and underprescription of tetanus immunoglobulinen.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23665

Bron
NTR

Verkorte titel
T-PEP

Aandoening

tetanus prophylaxis after wounding on emergency department

Ondersteuning

Primaire sponsor: National Institute for Public Health and the Environment (RIVM)
Overige ondersteuning: National Institute for Public Health and the Environment (RIVM)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study endpoint will be the immune status as determined by the TQS (adequately protected versus insufficient protected), cut-off 0.1 IU/ml. and the use of tetanus post-exposure prophylaxis (yes/no). The immune status as assessed by the TQS will be related to the anamnestic vaccination history, i.e. adequately immunized with time since the last vaccination (more or less than 10 years since the last vaccination) or not or incompletely

immunized.
Over- and under-prescription of tetanus post-exposure prophylaxis will be assessed both for tetanus vaccination and TIG.

A comparison will be made between the immune status determined by the vaccination history and the immune status as a result of the TQS. A questionnaire will be used to record the vaccination status determined by the attending health care professional during anamnestic history. The frequency of over- and under-prescription of post-exposure prophylaxis will be determined.
The indication for post-exposure prophylaxis will be based on the advice of the Dutch National Health Council (GR) in 2003 that is the basis of the current nationwide guidelines.

The immune status due to the result of the TQS test will be stated as protected or unprotected.

There will be a distinction between the two different age cohorts as mentioned earlier, born before 1951 or after 1950. The two age cohorts will be distinguished to assess the relation between tetanus prophylaxis (tetanus vaccination and TIG) and the result of TQS.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Tetanus is a serious infectious disease, which can be lethal without treatment. Routine vaccination for tetanus since 1954 in the National Immunization Program (NIP) with high vaccination coverage, has resulted in very high seroprevalence of tetanus antibodies in the Dutch population. Each year about 2 to 3 cases of tetanus are reported. Almost all of these cases occur among not (fully) immunized elderly people who have not been eligble for routine vaccination. After wounding, people without a sufficient vaccination status can be protected by the administration of tetanus immunoglobulin (TIG) and/or (re)vaccination with tetanus toxoid.(TT) The high seroprevalence probably implicates that tetanus toxoid is given often to individuals that are already protected. On the other hand there are certain groups (i.e. people too old to be eligible for vaccination) who have lower seroprevalence rates and recently some cases were notified among this group whom have not been given TIG. The indication for (re)vaccination and TIG is complicated since health care personnel has to rely on self-reported vaccination history that might not be reliable. Recently the Tetanus Quick Stick (TQS) has become available. This instrument measures the immunity against tetanus and might help to decide whether a patient is at risk for contracting tetanus.

Objective:

The aim of this study is to find out whether TIG and revaccination prescription is in accordance with the immune status of a patient as measured by the TQS. Furthermore, the secondary objective is to assess whether or not the TQS might be of additional value in decision making for prophylaxis for specific age groups.

Study design:

Cross-sectional study.

Study population:

Patients visiting one of the three participating emergency departments (ED) with a wound will be asked to participate when they are 18 years of age or older and not in need for direct medical intervention. Two different age cohorts will be included, one with people born before 1951 and one with people born in 1951 or thereafter. In total 800 patients will be included.

Main study parameters/endpoints:

The percentage under- and overprescription of tetanus post-exposure prophylaxis in the different age groups with and without adequate tetanus antibody levels as determined by the TQS.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Participating in this clinical research, will extend the visit at the ED with a few minutes. Participants will not suffer from a different risk compared to people who are not participating, because they will receive routine care. Main benefit is that when people have low levels of antibodies as measured by the TQS, while based on the reported vaccination status TIG and/or (re)vaccination were not indicated, they will receive proper post-exposure prophylaxis and therefore will be adequately protected against tetanus.

Doel van het onderzoek

Using vaccination history as a representative for a persons immune status leads to overprescription of tetanus toxoid and underprescription of tetanus immunoglobulinen.

Onderzoeksopzet

Cross-sectional study.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Participants need to be at least 18 years old;

2. Participants with all types of wounds visiting one of the three emergency departments.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients younger than 18 years old;

2. Patients with severe injuries requiring immediate care or surgery.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2012
Aantal proefpersonen:	800
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-07-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39071
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3381
NTR-old	NTR3530
CCMO	NL39940.100.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39071

Resultaten

Samenvatting resultaten
N/A