

Tetanus post-exposure prophylaxis

Published: 21-08-2012

Last updated: 15-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON39071

Source

ToetsingOnline

Brief title

Tetanus post-exposure prophylaxis

Condition

- Bacterial infectious disorders

Synonym

lockjaw

Research involving

Human

Sponsors and support

Primary sponsor: RIVM

Source(s) of monetary or material Support: Rijksinstituut voor Volksgezondheid en Milieu

Intervention

Keyword: antibody-levels, prophylaxis, tetanus, TQS

Outcome measures

Primary outcome

Immune status as a result of the TQS and as a result of the anamnestic vaccination history.

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

Secondary outcome

Not applicable

Study description

Background summary

Tetanus is a serious infectious disease, which can be lethal without treatment. Routine vaccination in the the National Immunization Programme with high vaccination coverage, has resulted in very high seroprevalence of tetanus antibodies in the Dutch population. Each year only 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 eligible 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. The high seroprevalence implicates that tetanus toxoid (TT) 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 and recently some cases were notified among this group whom have not been given TIG. The indication for (re)vaccination and TIG are 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 might help to decide whether a patient is at risk for contracting tetanus.

Study 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 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 burden and risks

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 level 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 prophylaxis and therefore will adequately protected against tetanus. .

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

- Participants need to be at least 18 years old.
- Participants with all types of wounds visiting one of the three emergency departments.

Exclusion criteria

- Patients younger than 18 years old.
- Patients with severe injuries requiring immediate care or surgery

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 08-10-2012

Enrollment: 800

Type: Actual

Ethics review

Approved WMO

Date:	21-08-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	02-04-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23665
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL39940.100.12
Other	NTR13149
OMON	NL-OMON23665