VIM-positive Pseudomonas aeruginosa - the pre-SAMPAN study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24069

Source
Nationaal Trial Register

Brief title
Pre-SAMPAN

Health condition

VIM-positive Pseudomonas aeruginosa carriage

Sponsors and support

Primary sponsor: Not applicable
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

The main study endpoint is finding positive body sites of VIM-positive P. aeruginosa, other than the standard surveillance culture sites.

Secondary outcome

Secondary endpoints are patient characteristics favouring specific body sites being colonized by VIM-positive Pseudomonas aeruginosa.

Study description

Background summary

Currently, throat and rectum samples are the standard body sites for surveillance cultures to identify patients with Verona Integron-encoded Metallo-β-lactamase (VIM)-positive Pseudomonas aeruginosa (VIM-PA). Pseudomonas aeruginosa in general favours moist areas. Therefore, it is likely that VIM-PA has the ability to colonize other body sites as well. It is unknown, however, to which extent patients are also culture positive at other body sites, for example the navel, the ears, or between the toes. Inclusion of additional body sites may increase the detection rate.

Study objective

VIM-positive Pseudomonas aeruginosa can be found in other body sites besides throat and rectum, which are currently used as the standard surveillance culture sites.

Study design

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Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria: All living patients aged >18 years old, known to be carrying VIM-PA or formerly carrying VIM-PA, with a signed consent sheet.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study: no informed consent.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-08-2021
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	17-08-2021

Application type: First submission

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
NTR-new	NL9674
Other	METC Erasmus MC : MEC-2021-0525

Study results