Prevalence of Tinea Pedis (athlete's foot) in people with intellectual disability in The Netherlands

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Study into the prevalence of Tinea Pedis in intellectually disabled people who receive care from one of four care providers in The Netherlands, either living in the community or in a centralised location. Study into the prevalence of the different...

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

Summary

ID

NL-OMON34890

Source
ToetsingOnline

Brief title
Prevalence of Tinea Pedis

Condition

- Fungal infectious disorders
- Epidermal and dermal conditions

Synonym
athlete's foot; dermatomycosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,deelnemende

zorgverleners

Intervention

Keyword: intellectual disability, prevalence, risk factors, Tinea Pedis

Outcome measures

Primary outcome

Prevalence of Tinea Pedis in percentage in our study population, including 95% confidence intervals. Prevalence of the pathogens (fungi) that cause Tinea Pedis identified in our population in percentage of the established cases, including 95% confidence intervals. Calculating odds ratios for five risk factors contributing to Tinea Pedis in the study population, including 95% confidence intervals.

Secondary outcome

Niet van toepassing.

Study description

Background summary

Tinea Pedis is a fungal infection (dermatomycosis) of the feet, with high prevalence in the normal population. At least 10 percent of the population will suffer from Tinea Pedis at least once in their life (life time prevalence). Literature study reveals that the prevalence of Tinea Pedis in intellectually disabled people has not been studied yet. Which risk factors contribute to the development of Tinea Pedis in this population is also as yet unknown.

Study objective

Study into the prevalence of Tinea Pedis in intellectually disabled people who receive care from one of four care providers in The Netherlands, either living in the community or in a centralised location. Study into the prevalence of the different pathogens (fungi) that cause Tinea Pedis identified in our study population. Study into five risk factors that contribute to the development of

Tinea Pedis in the study population.

Study design

Our study is a non-invasive observational, cross-sectional prevalence study in people with mild to profound intellectual disability. Participants will be semi randomly selected for inclusion into the study. The number of participants to be included into our study has been calculated at 690, in order to make statistically significant statements on the prevalence of Tinea Pedis and five risk factors in our study population. The presence of Tinea Pedis will be established by a physical examination and inspection of the feet of the participants. If the presence of Tinea Pedis is suspected then a culture will be performed. Risk factors will be examined through a questionnaire that will be either filled out by the participants themselves, their relatives or supervisors, completed by additional data from their medical files. All data will be processed anonymously and cannot be traced to any particular participant.

Study burden and risks

The physical examination will at most take ten minutes per participant. A physical burden can be the removal of socks and shoes (if not already taken off beforehand) and the inspection of the feet by the participating physicians, including touching the feet and possible manipulation of the feet in order to inspect the entire foot. When presence of Tinea Pedis is suspected then either a swab of the area will be made or loose skin will be collected using a pair of tweezers. The risk of any adverse physical reactions in our study is negligible. The risk of any adverse psychological reactions is negligible. If participants show resistance during the physical examination, then the examination will be aborted and a second attempt will be made at a later date. If during the second attempt the participant still exhibits resistance, then the examination will be aborted for good and the participant will no longer be included into our study. The definition of resistance will be according to the definition provided by the document *Verzet bij mensen met een verstandelijke handicap in het kader van de Wet medisch-wetenschappelijk onderzoek met mensen, gedragscode voor artsen bij beoordeling van verzet bij mensen met een verstandelijke handicap* (Resistance in people with intellectual disability as outlined in the Act Medical Scientific Study in people, code of behaviour for physicians when evaluating resistance in people with intellectual disability). Group relatedness is applicable because our study is into the prevalence of Tinea Pedis in people with intellectual disability and cannot be performed in people with normal intellectual ability.

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

intellectual disability
age 18 or over
living with and receiving care from one of the participating careproviders

Exclusion criteria

age under 18
No consent from participant or legal guardian

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-07-2010
Enrollment:	700
Type:	Actual

Ethics review

Approved WMO

Date:	07-07-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL31538.078.10