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Self-collection of skin samples to diagnose scabies

Submission date 29/07/2025	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 20/08/2025	**Overall study status** Ongoing	
Last Edited 20/08/2025	**Condition category** Infections and Infestations	

Plain English summary of protocol

Background and study aims
Scabies is an infectious skin disease characterised by intense itching. It is caused by microscopically small mites that live in the surface of the skin and can be transmitted between people by close contact. An increase in scabies infections has been reported worldwide in the past 10-20 years. In the Netherlands, the number of reported scabies cases increased by more than threefold in the past decade.
In most cases, scabies is diagnosed based on clinical assessment by a healthcare professional. Due to the variety of signs and symptoms, though, it is not always easy to make a clinical diagnosis. A common diagnostic technique for identifying scabies infections involves the scraping of skin lesions followed by microscopic examination. However, this technique may be less good at detecting a scabies infection if low numbers of scabies mites are present. Another diagnostic technique that is under investigation is polymerase chain reaction (PCR), which seems to be better able to detect infections, although only a limited number of studies have assessed this in clinical practice.
The increasing number of scabies cases may strain healthcare services, prompting us to explore whether patients without specific medical training can successfully collect their own skin samples for testing. Self-collection of skin samples may form a promising way to expand scabies testing services. This may also help to overcome barriers associated with attending (outpatient) scabies clinics, such as concerns about autonomy, inconvenience, stigma and privacy.
The main aim of this study is to see whether skin samples collected by patients themselves are as good for detecting scabies infections as samples collected by healthcare professionals.

Who can participate?
Adults (age 18 years or older) presenting to a participating scabies outpatient clinic or dermatology outpatient clinic in the Netherlands with suspicion of scabies.

What does the study involve?
Participants first perform self-sampling, consisting of skin scrapings and a subsequent skin swab. Sampling (skin scrapings and subsequent skin swabs) is then also performed by an experienced health care professional. All samples are tested for scabies in the lab by PCR. Participants are also asked to complete a questionnaire on their experience and what they think about self-sampling.

What are the possible benefits and risks of participating?
There is no direct benefit to participants over and above the standard of care they would receive anyway. There are no expected risks associated with participation and the additional burden on participants is minimal.

Where is the study run from?
The study is run from the Radboud University Medical Centre in Nijmegen, the Netherlands, in collaboration with the municipal health departments (GGD) of Utrecht and Amsterdam and the dermatology department of the Canisius Wilhelmina Hospital in Nijmegen.

When is the study starting and how long is it expected to run for?
February 2023 to December 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr M.B..B. McCall, Dr J.LA. Hautvast and Dr C.F.H. Raven, scrapestudie@radboudumc.nl

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NL86424.091.24

Study information

Scientific Title
Sensitivity of self-Collected skin sAmPling for scabiEs: a pilot study

Acronym
SCRAPE

Study objectives
The primary objective is to determine whether the sensitivity of self-collected skin sampling for scabies diagnosis is non-inferior to skin sampling by a professional. Secondary objectives are to compare the sensitivity of skin scrapings with that of subsequent skin swabbing for scabies diagnosis and to compare the sensitivity and specificity of PCR with those of microscopic examination on skin scrapings for diagnosing active scabies infection in untreated scabies suspected, clinical or confirmed patients.

Ethics approval required
Ethics approval not required

Ethics approval(s)

Study design
Multicenter cross-sectional diagnostic study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital, Other

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Scabies

Interventions
Adults presenting to routine (public) health facilities with suspicion of scabies first perform self-sampling consisting of skin scrapings and a subsequent skin swab. Sampling (skin scrapings and

subsequent skin swabs) is thereafter performed by an experienced health care professional. All samples are subjected to scabies PCR and (where possible) microscopy. Participants are also asked to complete a questionnaire on, amongst others, motivation for self-sampling, as well as barriers/facilitators encountered during this process.

Intervention Type
Other

Primary outcome measure
Positivity of self-collected samples (defined as qPCR- and/or microscopy-positive on self-collected skin scrapings and/or self-collected skin swab) compared with positivity of professionally collected samples (defined as qPCR- and/or microscopy-positive on professionally collected skin scrapings and/or professionally collected skin swab); all samples are collected at baseline

Secondary outcome measures
1. Positivity of skin scrapings (defined as qPCR- and/or microscopy-positive on self-collected and /or professionally collected skin scrapings) compared with positivity of skin swabs (defined as qPCR-positive on self-collected and/or professionally collected skin swabs) ; all samples are collected at baseline
2. Positivity by qPCR (defined as qPCR-positive on self-collected and/or professionally collected skin scrapings) compared with positivity by microscopy (defined as microscopy-positive on self-collected and/or professionally collected skin scrapings); all samples are collected at baseline

Overall study start date
23/02/2023

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. 18 years or older
2. Attending a participating scabies outpatient clinic or dermatology outpatient clinic with suspicion of scabies
3. Providing written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
144

Key exclusion criteria
1. Individuals not speaking or understanding the Dutch or English language
2. Individuals who have been diagnosed with scabies in the last four weeks and have started treatment
3. Individuals who have used ivermectin for other diagnoses than scabies in the last 6 weeks
4. Individuals younger than 18 years
5. Individuals with immunosuppressive conditions
6. Any other condition, finding or situation which, in the opinion of the investigator, may significantly increase the risk to the individual because of participation in the study, affect the ability of the individual to participate in the study or impair interpretation of the study data

Date of first enrolment
24/07/2024

Date of final enrolment
30/12/2026

Locations

Countries of recruitment
Netherlands

Study participating centre
GGD Utrecht
Stadsplateau 1
Utrecht
Netherlands
3521 AZ

Study participating centre
Canisius Wilhelmina Ziekenhuis (Polikliniek Jonkerbosch)
Burgemeester Daleslaan 27
Nijmegen
Netherlands
6532 CL

Study participating centre
GGD Amsterdam
Nieuwe Achtergracht 100
Amsterdam
Netherlands
1018 WT

Sponsor information

Organisation
Radboud University Medical Center

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Sponsor type
University/education

Website
https://www.radboudumc.nl

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal.

Intention to publish date
31/12/2027

Individual participant data (IPD) sharing plan

The dataset generated during and/or analysed during the current study will be stored for 15 years in a non-publicly available repository within the Radboudumc's domain, but may be made available for other research on scabies (as described in the participant information/consent form) upon reasonable request to the principal investigators (scrapestudie@radboudumc.nl). This dataset contains pseudonymised data on clinical diagnosis, scabies PCR results on skin samples and questionnaire responses.

IPD sharing plan summary

Stored in non-publicly available repository, Available on request