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Candida auris screening, surveillance and infection control

Submission date 12/12/2024	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 07/01/2025	**Overall study status** Ongoing	
Last Edited 23/01/2026	**Condition category** Infections and Infestations	

Plain English summary of protocol

Background and study aims

Since its discovery in 2009, Candida auris cases are rapidly increasing worldwide. In 2017 in Europe, over 600 cases were already reported and in 2021 the United States has reported thousands of cases. In addition to C. auris, an increase in other (drug-resistant) Candida species is also reported. People most at risk for severe Candida infections include those with a weakened immune system, patients undergoing large surgeries and those with indwelling vascular catheters in the intensive care unit (ICU). Because C. auris colonizes the human skin and has shown prolonged survival in the environment, it can cause large and persistent outbreaks in hospitals and other healthcare institutions across the globe. In Europe, C. auris major outbreaks have been reported in Italy, Spain and the UK, while this species has become endemic in Turkey and Greece. Of concern is that C. auris is often multi-drug resistant, leaving the clinician with little to no options for antifungal treatment. For the above reasons, C. auris is a major concern for our public health and is categorized as a critical fungal pathogen in the WHO global fungal priority pathogens list. Several cases of C. auris colonization have also been found in the Netherlands, but there are currently no active surveillance programs that monitor the epidemiology of (invasive) Candida infections. Furthermore, robust screening protocols are lacking, increasing the probability of C. auris outbreaks in the Netherlands. Given the rapidly changing epidemiology of C. auris and the potential for the emergence of other Candida species, it is critical to be prepared for import cases in the Netherlands. This study aims to set up the required infrastructure and protocols to allow early interventions when needed. To combat emerging Candida infections, this study aims to build a consortium with stakeholders, evaluate current surveillance systems, and develop optimal screening protocols for C. auris in Greece. There will also be work to enhance preparedness with genome sequencing and wastewater surveillance and verify methods through outbreak scenario training. There is overwhelming evidence from medical literature that the epidemiology of yeast is shifting. The results of this project will enable us to implement a search-and-destroy policy concerning C. auris and other emerging yeast pathogens, thereby preventing unwanted yeasts from becoming endemic.

Who can participate?

Patients with a positive yeast culture from blood or other sterile sites (WP2 and 4a); patients in the ICU and patients outside of the ICU that are in contact with C. auris-positive patients (WP3); and, patients tested positive for C. auris (WP4b)

What does the study involve?
Workpackage 2: Collect 100 yeast isolates from blood in 4 Dutch hospitals and use patient data to assess the ISIS-AR platform for studying invasive yeast in the Netherlands.
Workpackage 3: Screen up to 400 patients in an Athens hospital for C. auris at various body sites using different detection methods to determine the best screening protocol.
Workpackage 4A: Use 200 yeast isolates (100 from WP2 and 100 from additional sites) to establish a whole genome sequencing platform for rapid identification and genotyping of yeast, including C. auris.
Workpackage 4B: Evaluate the suitability of wastewater sampling for C. auris surveillance using isolates from routine MDRO screening in 4 Dutch hospitals.

What are the possible benefits and risks of participating?
In the retrospective part of the study, there are no benefits for the participants. In the prospective portion of the study conducted in Greece, patients might test positive for Candida auris, which may not have been identified otherwise. This could result in a more adequate treatment. Additionally, identifying positive cases enables the implementation of infection control measures, helping to prevent the further spread of C. auris to other patients.

There are no risks related to participation in the study.

Where is the study run from?
Netherlands National Institute for Public Health and the Environment, RIVM

When is the study starting and how long is it expected to run for?
May 2024 to May 2028

Who is funding the study?
1. ZonMw, Netherlands Organisation for Health Research and Development
2. Netherlands National Institute for Public Health and the Environment, RIVM

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
10150022310025

Study information

Scientific Title
Candida AUris screening, surveillance and infectTION control

Acronym
CAUTION

Study objectives
Infections with yeasts such as Candida auris have been rising worldwide, including in Europe. Dutch hospitals had multiple C. auris colonized patients recently, all imported. Infections with C. auris mainly affect immunocompromised patients and patients who underwent complex surgeries. Since C. auris can survive well on surfaces, this yeast can spread in healthcare facilities and cause outbreaks. C. auris is often resistant to many antifungal medications hampering the treatment of patients. These factors have contributed to listing C. auris on the WHO fungal priority list, in addition to C. parapsilosis, C. tropicalis and C. albicans. Since screening and surveillance are not well developed, the overview of the presence and spread of C. auris is limited. This project will develop accurate screening and surveillance of yeasts to be prepared for the emergence of C. auris and to be able to adequately respond if C. auris and other yeasts spread and cause outbreaks in the Netherlands.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 10/04/2024, Scientific Council of Attikon University Hospital (Rimini 1, Haidari, 12462, Greece; +30 210-583-1692; greps@attikonhospital.gr), ref: 226/22-3-2024

2. approved 22/09/2024, METC Oost-Nederland (Philips van Leydenlaan 25, Nijmegen, 6525EX, Netherlands; +31 024 3613154; METCoost-en-CMO@radboudumc.nl), ref: 2024-17538

Study design
Multicenter cross-sectional observational study

Primary study design

Observational

Study type(s)
Diagnostic, Screening

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

Interventions
Workpackage 2: 100 yeast isolates from blood, found during routine diagnostics in 4 Dutch hospitals, will be collected. The isolates, together with some patient information (age, gender) will be used to investigate whether the existing ISIS-AR platform provides sufficient data to study invasive yeast in the Netherlands.
Workpackage 3: To determine the best C. auris screening protocol including sampling method and body site, a maximum of 400 patients from a hospital in Athens, Greece, will be screened for C. auris at different body sites. The swabs will be analyzed using different detection methods.
Workpackage 4A: The 100 yeast isolates from WP2, together with an additional 100 yeast isolates from blood and other sterile sites collected at 2 more Dutch hospitals, will be included. These isolates will be used to set up a whole genome sequencing platform for rapid identification and genotyping of yeast isolates, including C. auris.
Workpackage 4B: The suitability of wastewater sampling for the surveillance of C. auris will be evaluated. C. auris isolates found during routine MDRO screening at the 4 participating Dutch hospitals will be used in the study to confirm if C. auris is present in the hospitals' wastewater.

Intervention Type
Not Specified

Primary outcome(s)
WP2: Determination and susceptibility testing is performed on the yeast isolates found in blood, using the hospitals' own protocols. The isolates will also be sent to the national reference center to verify the results using EUCAST.
WP3: The best body locations for screening of C. auris will be tested by taking swabs from different body sites. To determine the best method for the detection of C. auris, different methods for culturing and molecular detection (PCR and LAMP) are compared using the swabs.
WP4a: Determination and susceptibility testing will be done in the same manner as for WP2. The isolates collected for WP2 and WP4 will also be sequenced by the national reference center using Illumina sequencing.
WP4B: Wastewater samples will be collected once a month in each center, serving as background data, and partially as a negative control. When proven C. auris colonized patients are admitted, wastewater sampling can be intensified.

Key secondary outcome(s))
WP4B: All C. auris isolates found during MDRO screening at the participating hospitals will be send to the national reference center for determination, susceptibility testing using EUCAST, and whole genome sequencing using Illumina sequencing.

Completion date
01/05/2028

Eligibility

Key inclusion criteria
WP2 & WP4a: Patients with a positive yeast culture from blood or other sterile sites.
Added 23/01/2026: Inclusion was performed retrospectively and was completed in November 2025.

WP3: Patients in the ICU and patients outside of the ICU who were in contact with C. auris-positive patients.
Added 23/01/2026: Inclusion was completed in January 2026.

WP4b: Patients tested positive for C. auris.
Added 23/01/2026: Inclusion is still ongoing.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Total final enrolment
0

Key exclusion criteria
Patients who object to participation.

Date of first enrolment
01/11/2024

Date of final enrolment
01/05/2028

Locations

Countries of recruitment
Greece

Netherlands

Study participating centre
Amsterdam UMC
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Study participating centre
Erasmus MC
Dr. Molewaterplein 40
Rotterdam
Netherlands
3015GD

Study participating centre
Radboudumc
Geert Grooteplein Zuid 10
Nijmegen
Netherlands
6525GA

Study participating centre
University Medical Center Groningen
Hanzeplein 1
Groningen
Netherlands
9713GZ

Study participating centre
St. Antonius Ziekenhuis
Koekoekslaan 1
Nieuwegein
Netherlands
3435CM

Study participating centre
Laboratorium Microbiologie Twente Achterhoek
Boerhaavelaan 59
Hengelo
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7555BB

Study participating centre
University General Hospital 'Attikon'
Rimini 1

Haidari, Athens
Greece
12462

Sponsor information

Organisation
National Institute for Public Health and the Environment

ROR
https://ror.org/01cesdt21

Funder(s)

Funder type
Not defined

Funder Name
ZonMw

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Funder Name
Rijksinstituut voor Volksgezondheid en Milieu

Alternative Name(s)
Netherlands National Institute for Public Health and the Environment, RIVM

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study will be available upon request.

Findable: Data will be available upon request.
Accessible: There will be restrictions to access the data collection. The researchers involved in the project have first been given the opportunity to complete the analyzes and publish the results. After publication, the data in question will be made publicly available. If, after completion of the analyzes and publications, data from the bio-databases and other data have not been made public, a committee in office at that time will decide on further accessibility. Matters such as privacy of data, relevance, intent, commercial approach, conflicts of interest, etc. will be examined.
Interoperable: The data will be stored in such way (adapted to generic open standards) that other researcher can read the data collection.
Re-usable: All project participants have to give their permission for reuse of the data, and the data will be pseudonymised.

IPD sharing plan summary
Available on request