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# Can we use artificial intelligence for microscopic parasite diagnosis?

**Submission date**
06/10/2020

**Recruitment status**
No longer recruiting

**Registration date**
21/10/2020

**Overall study status**
Completed

**Last Edited**
14/04/2022

**Condition category**
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**Plain English summary of protocol**
Background and study aims
Optical microscopy remains the gold standard technique for diagnosing the cause of disease due to parasites, accounting for >60% of all parasite diagnosis. Physicians have been using the same technology since the 1820s, by manually reviewing samples under a microscope. This requires the time of an expert analyst at the right place and at the right moment as the sample is being taken, something not always available and affordable. With globalization, we are seeing an increasing number of parasitic diseases making diagnosis more challenging. This study aims to prove that a digital solution using artificial intelligence will reduce time, costs and distances of microscopy diagnosis.

Who can participate?
The samples have already been collected and detected positive for a parasite by the conventional method.

What does the study involve?
The study will deploy a high-tech cost-efficient digital platform that enables remote analysis of samples and Develop and Validating AI algorithms to support and improve the detection of these parasites using digitized microscopy images.

What are the possible benefits and risks of participating?
This study involves no apparent risks as collection and diagnosis of samples had already been completed in the past done by standard microscopy methods.
The study will evaluate the possible benefits of digitalization of collected preparations from subjects with suspected parasitological disease.

Where is the study run from?
The Coordinating centre is the National Microbiology Centre (Carlos III Public Health Institute, Madrid, Spain) and 3 other international centres: Universidad Mayor de San Simón. Cochabamba (Bolivia), Instituto Leônidas e Maria Deane, Fundação Oswaldo Cruz. Manaus (Brazil) and Medical Research Center (MRC), Kuala Lumpur (Malaysia)

When is the study starting and how long is it expected to run for?
September 2020 to June 2022

Who is funding the study?
This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 881062

Who is the main contact?
Dr. José Miguel Rubio, jmrubio@isciii.es

# Contact information

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Scientific

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
Nil known

# Study information

### Scientific Title
Evaluation of a digital health ecosystem using artificial intelligence for microscopic analysis of parasitological samples

### Study objectives
Optic microscopy is still the gold standard for diagnosing several tens of pathologies. This requires the
time of an expert analyst at the right place and at the right moment as the sample is been taken, something not always available and affordable. In addition, in recent years the WHO has been strengthening the diagnosis of high sensitivity and specificity under the premise that the only way to control infectious diseases is through a good diagnosis prior to correct treatment. In the case of parasitic diseases closely related to the poorest countries on the planet, those located in the tropical and subtropical zones, resources are restricted and all these new technologies with high sensitivity and specificity in general are expensive and difficult to incorporate into countries and regions where in many cases they do not have access nor to energy sources. The idea of this project is to maintain microscopy, as a primary diagnosis, improving its sensitivity and specificity, thanks to SpotLab's products which sit in the convergence of the physical and the digital world to reduce time, costs and distances of microscopy diagnosis. SpotLab's technology is based on three technological pillars. 1) a smartphone transformed into a portable, intelligent and low-cost medical device, 2) a flexible and easy to use telemedicine platform that can be tailored to multiple diagnosis protocols that is connected to the knowledge of worldwide physicians or experts; and 3) a factory of AI models that prioritizes cases and assists diagnosis for multiple pathologies.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 30/09/2020, Research Ethics Committee Instituto de Salud Carlos III (Avda. Monforte de Lemos 5. Pabellón 5. 28029, Madrid, Spain; +34 91 822 27 65; cei@isciii.es), ref: CEI PI74_2020

### Study design
Multi-centre observational study

### Primary study design
Observational

### Secondary study design

### Study setting(s)
Other

## Study type(s)
Other

## Participant information sheet
No participant information sheet available

## Health condition(s) or problem(s) studied
Blood parasites (malaria, filaria and other NTDs such as Chagas disease and Leishmania)

## Interventions
This is a multi-centre, observational study to evaluate the benefits of digitalization of collected preparations from subjects with a suspected parasitological disease. Generated data will be used to train AI algorithms for identification and counting of parasitic diseases. The development of the AI algorithm will consist of two phases:
Phase I: Digitalization of parasite images to generate a database for AI algorithm development
Phase II: Integration and evaluation of the AI model as a tool for assisting microbiologist experts in parasite detection and labeling

Processing and digitizing samples of the different parasitosis included in the study. Once the images are digitized, they are processed through TeleSpot creating a repository of images in real time.

A proportion of the analyzed images from the repository will serve to develop and improve the algorithms designed by SpotLab so that microscopic detection is improved through the use of artificial intelligence (AI). Once a database of annotated images is generated, images will be divided into training and validation dataset to comply with the statistical requirements for model validation. SpotLab will be in charge of training convolutional neural networks with the training data set in order to obtain AI algorithms for identification of parasitological samples. Identification performance will be tested by assessing the prediction quality of the algorithm in the validation set compared to the ground truth annotated by the specialist during the labelling phase. Only if precision (positive predictive value) and recall (sensitivity) of the AI algorithm generated after phase I are both higher than 90%, it will be possible to conduct phase II. In case precision values are higher than the proposed threshold and closer to 100% it is possible to consider recall values <90% if the integration of the AI assisted analysis in the user experience reports efficiency benefits to the users.

During phase II of the AI algorithm development, the total digitized images will be analyzed in TeleSpot with an AI tool that will automatically suggest the parasite detection and classification. Experts will have to manually revise all false-positive predictions made by the AI algorithm and to verify that those predictions were actually false positives and in case had an initial incorrect label correct and re-label them. Corrections will be used to train the AI model in a continuous process. During phase II, if the AI suggestions model does not perform as expected, additional analysis through TeleSpot may be conducted like it was done during phase I.

## Intervention Type
Device

## Phase
Not Applicable

## Primary outcome measure

1. Standard procedure for remote analysis of digitized parasitological samples, measured by the number of samples analysed by web platform (TeleSpot) and analysis time per sample
2. Repository of digitized parasite images with each parasitic form appearing in the image correctly marked and tagged measured by the number of tagged samples (images) for each parasitic form and % agreement among users (reviewers) throughout the study
3. Accuracy of the AI algorithm developed measured by % of agreement among experts and AI algorithm throughout the study
4. Usability report based on the results from SUS scale and specific product questionnaires evaluating the remote analysis process at the beginning and the end of the study

### Secondary outcome measures
There are no secondary outcome measures

### Overall study start date
01/09/2020

### Completion date
30/06/2022

## Eligibility

### Key inclusion criteria
1. All preparations likely to be positive for a parasite from the laboratory sample collection that are properly stained and where the morphology of the parasite is well preserved.
2. All preparations that have been previously anonymized without the possibility of reversing the coding.

### Participant type(s)
Other

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
The minimum number of slides to be analysed for malaria is 90 slides, for tripanosomiasis is 30, for leishmaniasis is 20 and for filariasis is 69

### Key exclusion criteria
1. All preparations that are not properly stained and the morphology of the parasite is not well preserved
2. All those preparations that have not been previously anonymized

### Date of first enrolment
01/01/2021

### Date of final enrolment
31/12/2021

# Locations

## Countries of recruitment
Bolivia

Brazil

Malaysia

Spain

## Study participating centre
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## Study participating centre
**SpotLab S.L.**
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## Study participating centre
**Parasitological Department. Medical Research Center (MRC)**
Jalan Pahang
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## Study participating centre
**Biodiversity Laboratory. Fundação Oswaldo Cruz - Instituto Leônidas e Maria Deane**
Rua Terezina, 476 - Adrianópolis
Manaus
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## Study participating centre

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# Sponsor information

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SpotLab S.L.

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**Sponsor type**
Industry

**Website**
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# Funder(s)

**Funder type**
Government

**Funder Name**
European Union’s Horizon 2020 research and innovation programme under grant agreement No 881062

# Results and Publications

**Publication and dissemination plan**
The main and/or partial results obtained from the project will be made public within 12 months of reaching the end of the study. The end of the study is the time point at which the last data items are to be reported, or after the outcome data are sufficiently mature for analysis. Partial or advance results could be presented in international congresses, workshops, professional meetings, conferences or other scientific forums. In any case, any publication, including

presentations in congress or conferences, must have the approval of all partners, establishing an order of priority for authors that is fair, equal and representative of the work performed that will be discussed in each case. A full report of the outcomes should be made public no later than two years after the end of the study. All publications will be made in high-impact peer-reviewed Open Access Journals to follow the recommendations of the European Commission.
Any other public disclosure including press releases, professional meetings, marketing purposes or similar shall be subject to the mutual approval of the partners, which approval shall not be unreasonably withheld or delayed. Any written disclosure will be sent to the partners within 20 days prior to its publication for review.

## Intention to publish date
01/09/2022

## Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

## IPD sharing plan summary
Data sharing statement to be made available at a later date

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Basic results | | 14/04/2022 | 14/04/2022 | No | No |