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Can we use artificial intelligence tools for automatic analysis of bone marrow samples?

Submission date
24/11/2020

Registration date
11/12/2020

Last Edited
13/04/2022

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Other

[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 several tens of pathologies by manually reviewing samples under a microscope. Microscopic examination and classification of cells that form blood cells is a critical step for the diagnosis of blood diseases. However, it is a laborious, time-consuming technique and its results are subject to the expert examining the sample. Bone marrow aspiration (BMA) biopsies are carried out in order to diagnose many blood diseases, such as leukaemia.
This study aims to prove that the proposed digital solution will reduce time, costs and distances of microscopy diagnosis. To do so, we are generating a correctly annotated database that can be used to train Artificial Intelligence models that will help in blood disease diagnosis.

Who can participate?
Subjects with suspected hematological diseases attending 12 Octubre Hospital for a BMA procedure who are willing to provide a bone marrow sample. Also, professional hematologists who are expert at analyzing the bone marrow samples will participate.

What does the study involve?
Patients will provide a bone marrow sample that will be analysed using the AI system and also by a number of experts. The agreement between the expert analysis will be measured. Also the experts will fill in questionnaires assessing their satisfaction with the AI system.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Hospital Universitario 12 de Octubre (Spain)

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

Who is funding the study?
European Union Horizon 2020

Who is the main contact?
Dr María Linares (scientific), mlinares@ucm.es
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
v2.0

Study information

Scientific Title
Evaluation of a digital ecosystem leveraging mobile technology and artificial intelligence for digitalization and remote analysis of bone marrow samples

Acronym
MEDUL-AI

Study objectives
The proposed system will convert the current microscopes into digital microscopes connected to a comprehensive cloud platform that will enable images of BMA samples to be archived securely for remote review and clinical management. The possibility of a standardized digitalization of microscopy smears dramatically enhances diagnosis capabilities, as it enables remote diagnosis, second clinical opinion consultations, and helps to achieve automatization of the procedure as it serves as a way of gathering data to develop artificial intelligence tools that will ease the diagnosis process.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/11/2020 Ethics Committee of Clinical Research Hospital Universitario 12 de Octubre (Av. de Córdoba s/n 28041 Madrid, Spain; +34 91 7792613; maria.ugalde@salud.madrid.org), ref: CEIm: 20/430

Study design
Single center observational

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Training of convolutional neural network algorithms for identification and counting of cellular lineages and specific cell types of bone marrow

Interventions
This is a one-centre, observational study to evaluate benefits of digitalization of collected BM samples in Hospital Universitario 12 Octubre from patients with suspected hematological disease. Generated data will be used to train convolutional neural network algorithms for identification and counting of cellular lineages and specific cell types of bone marrow.

The samples will belong to patients visiting the hematology outpatient clinic for a BMA procedure at Hospital Universitario 12 Octubre (Madrid).
The execution of the study consists of 2 phases:
Phase 1: Digitalization of routine procedure for BMA analysis of Hospital 12 de Octubre, and generation of BMA tagged image database for AI algorithm development.
Phase 2: Integration and evaluation of AI model as a tool for assisting hematologists in cell counting of BMA samples.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
1. Number of samples analysed by web platform (TeleSpot) and analysis time per sample
2. Professionals' satisfaction measured with the new system measured by a usability report based on the results from a system usability scale (SUS) and AdaptaSpot Usability Questionnaire evaluating the remote analysis process. The SUS and the product questionnaires are completed every three months during the length of the study

Key secondary outcome(s))
1. Number of digitized bone marrow aspirate images correctly marked and tagged
2. Accuracy of the AI algorithm developed and the % of agreement among experts and AI algorithm. Cell-type classification 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.

Completion date
30/05/2022

Eligibility

Key inclusion criteria
Patients:
1. Suspected hematological disease
2. Signed informed consent

Bone marrow samples:
1. Good quality BMA sample (with proper staining and lump to provide sufficient quality and quantity)

Professionals/experts:
1. Sanitary professionals of the National Health System (Doctors, Cytologists) working at Hematology Department of the Hospital Universitario 12 Octubre with microscopy experience on hematological diseases

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria

Patients:
1. Individuals unwilling to participate in the study
2. Unspecified reasons that, in the opinion of the investigator or sponsor, make the subject unsuitable for enrollment

Bone marrow samples:
1. BMA samples that do not have a good quality stain
2. BMA samples with insufficient lump

Date of first enrolment

17/05/2021

Date of final enrolment

31/03/2022

Locations

Countries of recruitment

Spain

Study participating centre
Hospital Universitario 12 de Octubre

Av. de Córdoba s/n
Madrid
Spain
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Study participating centre
SpotLab S.L.

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Sponsor information

Organisation

SpotLab S.L.

Funder(s)

Funder type
Government

Funder Name
Horizon 2020 (grant no. 881062)

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

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		13/04/2022	13/04/2022	No	No