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Can images of the eyes be used to develop a reliable, non-invasive method for categorising the severity of jaundice?

Submission date 08/05/2026	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 29/05/2026	**Overall study status** Ongoing	
Last Edited 29/05/2026	**Condition category** Signs and Symptoms	

Plain English summary of protocol

Background and study aims
Jaundice is often characterised by the yellowing of the skin and the whites of the eyes (sclera) due to elevated blood bilirubin levels. Bilirubin is an orange-yellow pigment formed by the breakdown of red blood cells. Jaundice can indicate serious health issues, including liver disease. Clinicians often rely on the characteristic yellow tint of the sclera to detect jaundice, but this method is subjective and varies significantly among clinicians, usually requiring an invasive blood test for confirmation. This study aims to collect images of participants' eyes, along with their existing bilirubin level result, to develop a model that can categorise the severity of jaundice based on these images.

Who can participate?
Patients aged 18 years and over admitted to York and Scarborough Teaching Hospitals NHS Foundation Trust

What does the study involve?
Patients who consent to take part will be asked to look into a box-like device with a camera attached so a photograph of the eyes can be taken. The bilirubin level from a recent blood test will be used alongside the images. No additional blood tests or invasive procedures are involved. This process should take about 5 to 10 minutes. Afterwards, patients will ask you a few questions to assess their satisfaction of the imaging process. There is no further follow-up required.

What are the possible benefits and risks of participating?
There are no direct benefits and no risks associated with taking part.

Where is the study run from?
The University of York (UK)

When is the study starting and how long is it expected to run for?
March 2026 to September 2026

Who is funding the study?
Engineering and Physical Sciences Research Council (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
344432

Central Portfolio Management System (CPMS)
70336

Study information

Scientific Title
Mechanised measurement of icterus from sclera tinge yellowness in hospital patients

Acronym
MiSTY

Study objectives
1. Can images of the eyes be used to develop a reliable, non-invasive method for categorising the severity of jaundice?
2. How accurately can the developed non-invasive method categorise different levels of jaundice severity compared to traditional blood tests, and what is the minimum serum bilirubin level it can reliably detect using eye images?

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/09/2025, London - Camden & Kings Cross Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; camdenandkingscross.rec@hra.nhs.uk), ref: 25/PR/1201

Primary study design
Interventional

Allocation
N/A: single arm study

Masking
Open (masking not used)

Control
Uncontrolled

Assignment
Single

Purpose

Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Symptoms and signs involving the digestive system and abdomen

Interventions
Participants will be adult in-patients with blood bilirubin measurements available from routine blood tests taken as part of their standard care. Their initial location of treatment will include the Emergency Department, Medical and Surgical Wards, and High Dependency Units. The hospital's biochemistry department will provide bilirubin test results, typically available within one to three hours after the blood sample is processed. Twice daily, the study manager will review the results to identify potential participants with serum bilirubin levels greater than 21 µmol/l. An equal number of patients with levels below 21 µmol/l will be randomly selected using a random number generator to form a control group.

Identified individuals will be assessed against the inclusion and exclusion criteria. Those meeting any exclusion criteria will not be invited to participate. Eligible individuals will be approached by a research nurse, who will provide a participant information sheet explaining the study and obtain informed consent.

Once consent is given, the participant's eyes will be photographed to capture images of the sclera. This non-invasive process will take about 10 to 15 minutes. No additional blood tests or invasive procedures will be required, and participants can return to normal activities immediately after. The eye images will be linked to the participant's recent bilirubin results to help train a machine-learning model for classifying jaundice severity.

Participants will not need follow-up, and their involvement will end once imaging is complete. All data will be pseudonymised, with access restricted to authorised personnel. Participants can withdraw consent at any time without affecting their medical care.

Intervention Type
Other

Primary outcome(s)
1. The accuracy of the Convolutional Neural Network (CNN) classification of jaundice severity based on eye images compared to the ground truth serum bilirubin level as determined by blood tests, measured using metrics such as sensitivity, specificity, and overall agreement between the CNN classifications and the actual serum bilirubin measurements, at a single timepoint

Key secondary outcome(s))
There are no secondary outcomes

Completion date
30/09/2026

Eligibility

Key inclusion criteria

1. Willing and able to give informed consent for participation in the study
2. Male, female, or other, aged 18 years and above
3. Able, in the investigator's opinion, and willing to comply with all study requirements
4. Can be feasibly consented and measured within 48 hours of their blood test
5. Can be either mobile or immobile but must be capable of opening their eyes for the photograph
6. Currently admitted to the hospital as an inpatient
7. Deemed suitable to approach by the clinical ward team

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Intoxicated or under the undue influence of drugs or medications
2. Advanced eye pathology, as determined by the patient or clinician
3. Periorbital or orbital cellulitis
4. Implantable or non-removable contact lenses
5. Inability to obtain a scleral photographic image within 48 hours of the blood test
6. Epilepsy
7. Cataracts

Date of first enrolment
18/03/2026

Date of final enrolment
30/09/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
York and Scarborough Teaching Hospitals NHS Foundation Trust
York Hospital
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Sponsor information

Organisation
University of York

ROR
https://ror.org/04m01e293

Funder(s)

Funder type
Government

Funder Name
Engineering and Physical Sciences Research Council

Alternative Name(s)
UKRI Engineering and Physical Sciences Research Council, Engineering and Physical Sciences Research Council - UKRI, Engineering & Physical Sciences Research Council, Science Research Council, Science and Engineering Research Council, EPSRC, SRC, SERC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date