ISRCTN69711307 https://doi.org/10.1186/ISRCTN69711307

Evaluating a new test for blood disorders

Submission date 05/05/2026	**Recruitment status** Recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/05/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 11/05/2026	**Condition category** Other	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Some people have a condition called monoclonal gammopathy, where an unusual protein is found in the blood. This can sometimes be an early sign of blood cancers such as myeloma, so it needs regular monitoring. At the moment, monitoring involves blood samples taken from a vein in the arm and sent to a laboratory. This study aims to find out whether a new finger prick blood test, called the MySELF test, gives results that are as accurate as the standard laboratory blood tests. The study also aims to understand how acceptable and practical this finger prick test is for patients and healthcare staff.

Who can participate?
Adults aged 18 years or over who are already having blood tests for monoclonal gammopathy as part of their routine NHS care can take part. Participants need to be willing to have a small finger prick blood sample and be able to provide informed consent. Healthy volunteers aged 18 to 100 years may also take part to help with test development.

What does the study involve?
Participants will have the MySELF finger prick test carried out at around the same time as their usual blood tests. For most people this will happen once. Some participants who already have repeated blood tests as part of their care may be asked to have the finger prick test several times, up to a maximum of six occasions, alongside their routine blood samples. Participants will also be asked to complete a questionnaire about their experience of the test. The finger prick test will always be done within 72 hours of the standard blood test so the results can be compared.

What are the possible benefits and risks of participating?
There may be no direct health benefit from taking part. However, the study may help improve future care for people with monoclonal gammopathy by making testing quicker and more convenient. The risks are minimal and mainly relate to the finger prick blood sample, which may cause brief discomfort or minor bleeding.

Where is the study run from?
University Hospitals Birmingham NHS Foundation Trust, with oversight from the University of Birmingham (UK).

When is the study starting and how long is it expected to run for?
February 2026 to May 2027.

Who is funding the study?
The study is funded by Cancer Research Horizons and is sponsored by the University of Birmingham (UK).

Who is the main contact?
Dr Tracey Chan, tracey.chan@uhb.nhs.uk

Contact information

Type(s)
Principal investigator, Public

Contact name
Dr Tracey Chan

ORCID ID
https://orcid.org/0000-0003-1538-8485

Contact details
Centre for Clinical Haematology
Mindelsohn Way
Birmingham
United Kingdom
B15 2GW
+44 121 371 9501
tracey.chan@uhb.nhs.uk

Type(s)
Scientific

Contact name
Dr Jennifer Heaney

ORCID ID
https://orcid.org/0000-0002-2928-9712

Contact details
Clinical Immunology Service - University of Birmingham
3rd Floor, No.1 Birmingham Health Innovation Campus (BHIC)
Aston Webb Boulevard
Birmingham
United Kingdom
B29 6TH
+44 121 414 4069
j.l.j.heaney@bham.ac.uk

Additional identifiers

Integrated Research Application System (IRAS)
352718

Protocol number
RG_25-029

Study information

Scientific Title
A structured evaluation of a lateral flow test to monitor monoclonal gammopathy compared to standard of care serum testing to improve early diagnosis of myeloma

Acronym
MySELF

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/08/2025, West Midlands - Black Country Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8094; blackcountry.rec@hra.nhs.uk), ref: 25/WM/0134

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Monoclonal gammopathies

Interventions
The MySELF study is an observational, prospective cohort study which identifies patients who will be having blood taken via phlebotomy for sPEP and sFLC testing, as part of their planned clinical care. In parallel, they will undergo the MySELF test and complete a questionnaire on their experiences of the test to provide feedback on the process.
For most patients, this will be a one-off test but a cohort of patients, who are already undergoing repeated sPEP and sFLC testing as part of their planned clinical care, will be asked if they are happy to provide repeat MySELF tests at the same time as their routine blood samples (up to a maximum of six timepoints). For the purposes of test development, there should be at least 1 week intervals between sequential tests. However, in the majority of cases, routine monitoring is performed every 3-4 weeks or 2-3 months to coincide with treatment schedules and clinic appointments.
This should include:

a) Individuals (minimum N=20) who are likely to have stable levels of monoclonal gammopathy over the test time points. These individuals will be identified from outpatient clinic and inpatient lists as patients with known monoclonal gammopathy who are not receiving treatment that is likely to change the monoclonal gammopathy levels. This will identify whether the test is able to accurately track stable disease.
b) Individuals (minimum N=20) who have fluctuating levels of monoclonal gammopathy. These individuals will be identified from outpatient clinic and inpatient lists as patients with known monoclonal gammopathy with progressive disease, or are receiving therapy that is likely to change the monoclonal gammopathy levels. This will identify whether the MySELF test is sensitive to change in patient levels over time.

These patients will be having routine blood tests (i.e. full blood count, biochemistry and including standard of care monoclonal gammopathy tests) as part of their standard NHS clinical care. We will perform parallel MySELF tests in these patients to enable comparison. For all patients (up to N=500), the MySELF test will be performed within 72 hours of the standard of care sPEP and sFLC tests.

The MySELF test will also be evaluated using healthy donors (up to N=100) recruited from the University of Birmingham and local community. Existing ethical approval is already in place (ethical approval from University of Birmingham; ERN_17_213) for collecting blood samples from healthy donors for the purposes of test development.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
MySELF test

Primary outcome(s)
1. Determine the sensitivity and specificity of the point of care MySELF test in monoclonal gammopathies measured using MySELF test result correlation with the standard of care serum tests - serum protein electrophoresis and serum free light chain - as a reference at Within 72 hours

Key secondary outcome(s)
1. Determine overall acceptibility of the MySELF test to patients measured using a novel questionnaire at immediately after test administration

2. Determine overall acceptability of the MySELF test to nursing team measured using a novel questionnaire at after test administration

Completion date
10/05/2027

Eligibility

Key inclusion criteria

1. Age >18 years
2. Undergoing sPEP and sFLC serum testing as part of routine clinical care
3. Willing to undergo finger prick blood sampling
4. Able to provide informed consent

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Outside of stated age range
2. Unable or unwilling to provide informed consent

Date of first enrolment
10/02/2026

Date of final enrolment
10/02/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
England
B15 2GW

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type

Funder Name
Cancer Research Horizons

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available