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A new home saliva test to help diagnose adrenal insufficiency: finding out how well it works in the NHS

Submission date
17/11/2026

Recruitment status
Not yet recruiting

Registration date
25/11/2026

Overall study status
Ongoing

Last Edited
25/11/2026

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Adrenal insufficiency is a condition where the body does not produce enough of a hormone called cortisol. Cortisol is important for helping the body cope with illness, injury and stress. People with adrenal insufficiency can experience symptoms such as tiredness, dizziness, feeling sick and muscle aches. If the condition is not diagnosed and treated, it can lead to a serious, potentially life-threatening illness called an adrenal crisis.
Currently, people who may have adrenal insufficiency usually need blood tests or a hospital-based test called a short synacthen test. This test involves having an injection and several blood tests over an approximately 2-hour period. It can also involve long waiting times and travelling to hospital.
A new test called a waking salivary cortisone (WSC) test offers another way of testing for adrenal insufficiency. It involves collecting a saliva sample at home shortly after waking up. The sample is then sent to a laboratory to measure cortisone levels (the equivalent of cortisol in saliva).
Previous research suggests that this test can help identify people who are unlikely or likely to have adrenal insufficiency, potentially reducing the need for hospital-based testing.
This study aims to find out how well this home saliva test can be introduced and used across different NHS hospitals. The study will:
1. Find out how often healthcare professionals use the saliva test instead of existing tests
2. Understand what helps or makes it difficult for NHS hospitals to introduce the new test
3. Find out what patients and parents think about using the test at home
4. Explore whether the new test could save time and money for patients and the NHS
5. Develop guidance to help other NHS hospitals introduce the test in the future

Who can participate?
Patients having adrenal insufficiency testing as part of their usual NHS care will be included in the evaluation of how the new test is introduced and used. Patients do not need to give individual consent for their routine healthcare information to be included in this part of the study. However, people who have registered with the NHS England National Data Opt-Out will not have their information included.

What does the study involve?
The study will introduce the home saliva test into four NHS hospitals and look at how it is used in everyday healthcare. The study will involve three main stages:
1. Before introducing the test: Collecting information about how people are currently tested for adrenal insufficiency.
2. Introducing the test: Supporting the four NHS hospitals to start using the home saliva test and providing training for healthcare professionals and laboratory staff.
3. After introducing the test: Collecting information for a further 12 months to see how the new test is being used and whether it has improved testing services.
At each of these stages, the research team will collect information on a monthly basis from the four hospitals. They will look at:
1. How many people have the saliva test compared with existing blood and hospital tests
2. How many samples are successfully collected and returned
3. How long people wait for their test and results
4. How many people need further hospital-based testing
5. Whether introducing the saliva test changes the costs of testing
This study is not a trial in which patients are randomly allocated to different tests. Healthcare professionals will continue to decide which tests are appropriate for each patient.
Around 320 adults and 80 parents or legal guardians of children who are offered the saliva test will be invited to complete a short questionnaire. The questionnaire will ask about their views on the test, including how easy it was to use and whether they found it acceptable. People can complete the questionnaire online, by post or, where needed, with help over the telephone.
Healthcare professionals and laboratory staff involved in introducing the test will be invited to take part in interviews. The interviews will explore what worked well, any difficulties they experienced and what could be improved when introducing the test into NHS services.

What are the possible benefits and risks of participating?
The study may help improve the way people are tested for adrenal insufficiency in the future. The home saliva test could:
1. Reduce the number of hospital visits needed for testing
2. Avoid the need for needles and injections for some people
3. Make testing more convenient for adults and children
4. Reduce waiting times for diagnosis
5. Help the NHS save time and money
There may not be a direct benefit to people whose information or questionnaire responses are included in the study.
The saliva test will be introduced as part of usual NHS care. Patients will not be recruited as research participants and decisions about which tests patients need will remain with their healthcare professionals.
The study will use confidential patient information. Steps will be taken to protect this information, including removing personal details before information is shared with the wider research team. Patients will also have the option for their data not to be collected for the purposes of this research using the National Data Opt-Out service.

Where is the study run from?
The study is led by researchers at the University of Sheffield, Sheffield Teaching Hospitals NHS Foundation Trust, the University of Hull and Manchester University Hospital NHS Foundation Trust (UK), working in partnership with the four participating NHS Trusts:
1. King’s College Hospital NHS Foundation Trust
2. Leeds Teaching Hospitals NHS Trust
3. Royal Cornwall Hospitals NHS Trust

4. University Hospitals of Leicester NHS Trust
Hull Health Trials Unit at the University of Hull will support the management of the study.

When is the study starting and how long is it expected to run for?
January 2027 to June 2029

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
1. Dr Charlotte Elder, c.j.elder@sheffield.ac.uk
2. Prof. Miguel Debono, miguel.debono@nhs.net

Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
351793

Central Portfolio Management System (CPMS)
65672

National Institute for Health and Care Research (NIHR)
174395

Study information

Scientific Title
Evaluating the implementation and uptake of waking saliva cortisone: a new home-based test for adrenal insufficiency

Acronym
RE-SCAIT

Study objectives
Primary objective:
1. To measure clinician uptake of waking salivary cortisone (WSC) testing as a replacement for conventional testing

Secondary objectives:
1. To identify facilitators and barriers to implementation in different types of hospital
2. To assess the costs of offering WSC versus current testing for adrenal insufficiency
3. To refine an implementation strategy to facilitate widespread rollout of WSC testing, if appropriate

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/11/2026, Wales Research Ethics Committee 4 (Health and Care Research Wales, Floor 4, Crown Building, Cathays Park, Cardiff, CF10 3NQ, United Kingdom; -; Wales.REC4@wales.nhs.uk), ref: 26/WA/0318

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
Adrenal insufficiency

Interventions
This is a mixed methods study with a series of interlinked work packages to evaluate the roll out and impact of waking salivary cortisone (WSC) testing in four NHS Trusts. The study will utilise an interrupted time series design, collecting data before and after the implementation of the test in order to observe changes in practice over time.

Routinely collected data will be provided by participating sites on a monthly basis during three study phasis: a pre-implementation phase (consisting of a 12-month retrospective data collection), a 3-6-month implementation phase or embedding period as WSC testing is established at the site, and then a 12-month post-implementation prospective data collection.

Data relating to the study outcomes will be collected locally at sites in a central shared access spreadsheet and will be pseudonymised at source through the removal of direct identifiers and assignment of a unique study ID number. Only pseudonymised datasets will then be transferred to the University of Hull Data Safe Haven for analysis.

The interrupted time series data collection will also be supported by an embedded qualitative process evaluation and health economic modelling. The process evaluation will include qualitative interviews with healthcare professionals within in participating Trust to gain their view on implementing WSC testing, and a patient questionnaire for the first 100 patients (80 adults and 20 parents/legal guardians of children) offered a WSC at each site for insight into the

acceptability of the test. These will enable identification of facilitators and barriers to implementation in the different Trusts.

The model-based economic evaluation will use the interrupted time series analysis to estimate the proportion of patients receiving each type of adrenal insufficiency test before and after the implementation of WSC, to estimate an average cost per patient for adrenal insufficiency testing within the endocrine service. This will be used to determine the average cost saving for sites implementing the new test.

Findings from the study will be shared and discussed in Knowledge Exchange Workshops, which will be used to refine a final implementation strategy for future rollout across the NHS.

Intervention Type
Other

Primary outcome(s)
The number of waking salivary cortisone (WSC) tests requested as a proportion of the total requested adrenal insufficiency tests, collected as absolute numbers on a monthly basis

Key secondary outcome(s)
1. The number of usable WSC test results as a proportion of requested WSC tests, collected as absolute numbers on a monthly basis
2. Comparative adrenal function testing failure rate measured by comparing the proportion of usable WSC test results against the proportion of usable early morning cortisol (EMC) and Short Synacthen Test (SST) results on a monthly basis
3. Test turnaround time determined as the time from clinician decision to test to availability of the result to the clinician, assessed on a monthly basis
4. Patient acceptability of the test collected using a bespoke patient questionnaire sent to the first 100 patients to be offered the WSC test at each site at the start of the post-implementation phase
5. Healthcare professional experiences of implementation of the test pathway explored using qualitative interviews at the end of the main ITS study
6. Potential average cost savings for the typical Trust implementing WSC test measured using the proportion of patients receiving each test type to calculate the incremental costs for adrenal insufficiency testing, measured before and after WSC implementation

Completion date
30/06/2029

Eligibility

Key inclusion criteria
Patients having adrenal insufficiency testing as part of their usual NHS care will be included in the evaluation of how the new test is introduced and used. Patients do not need to give individual consent for their routine healthcare information to be included in this part of the study.

Healthy volunteers allowed
No

Age group

Adult

Sex
All

Total final enrolment
0

Key exclusion criteria
People who have registered with the NHS England National Data Opt-Out will not have their information included.

Date of first enrolment
01/01/2027

Date of final enrolment
30/06/2029

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leeds Teaching Hospitals NHS Trust
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Study participating centre
University Hospitals of Leicester NHS Trust
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Sponsor information

Organisation
University of Sheffield

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website			17/11/2026	No	No