ISRCTN17082829 https://doi.org/10.1186/ISRCTN17082829

Using artificial intelligence to diagnose 'glue ear' in children

Submission date	**Recruitment status**	[X] Prospectively registered
24/08/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/09/2021	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
20/09/2021	Ear, Nose and Throat	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Otitis media with effusion (OME) (also known as ‘glue ear’) is one of the most common causes of childhood hearing impairment and disability. It is estimated that more than 80% of children will have otitis media before the age of 10 years. This places a significant cost burden on the NHS with about 200,000 children with OME seen annually in primary care. Delayed diagnosis and poorly managed cases can result in severe and persistent OME with surgical treatment becoming the only management option, leading to long waiting times and excessively high costs for the NHS. Recent research into AI has made great progress in demonstrating its potential for the accurate diagnosis of OME. This novel research proves the capability of AI tools to diagnose OME automatically with an accuracy of 82%. The aim of this study is to achieve the best accuracy and reliability of these AI tools.

Who can participate?
Children under 12 years old who have been attending the clinic because parents/guardians are concerned about their hearing, or for a follow-up appointment after an acute case of ‘glue ear’.

What does this study involve?
The study involves a simple, fast, objective, and non-invasive middle ear measurement using a commercialised device called Wideband Absorbance Immittance (WAI) by Interacoustics after the patient has completed their routine hearing tests. Basically, a small probe will be placed in the patient’s ear canal, send some quiet clicks into their ear, and record the responses from the ear canal. The WAI test is performed by a clinical researcher and this procedure will be very quick (less than 1 minute per side).

What are the possible benefits and risks of participating?
The device should lead to significant and direct impacts on clinical assessment and diagnostic concepts for childhood OME in professional communities, and the NICE guidelines for childhood OME treatment. The benefits derived from its wider use as a diagnostic tool for accurate diagnosis of OME are summarised as follows. From the child development perspective, children with OME will benefit directly from prompt and accurate diagnosis and the application of appropriate management strategies tailored to support their ongoing development in areas such as speech and language development, education and future health. In this way, the

potential risks on the child’s social and future development that are associated with this condition will be removed. From the parents’ perspective, early and accurate diagnosis will help minimise parental concerns regarding their child's behaviour, performance at school, or language development, particularly where GPs primarily consult for the management of ear-specific symptoms only and do not start interventions immediately. The accurate, timely, efficient, equitable and patient-centred delivery of the enhanced quality healthcare will directly increase parental satisfaction. Because the WAI test is a simple, fast, objective, and non-invasive middle ear measurement using a commercialised device by Interacoustics after the participants have completed their routine hearing assessment, there should not be any significant risks in completing this study.

Where is this study run from?
Noah’s Ark Children’s Hospital for Wales and the Child Health Centre in St David’s Hospital, Cardiff (UK)

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

Who is funding this study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Fei Zhao
fzhao@cardiffmet.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Fei Zhao

ORCID ID
https://orcid.org/0000-0002-0936-4447

Contact details
200 Western Avenue
Cardiff
United Kingdom
CF5 2YB
+44 (0)2920417290
fzhao@cardiffmet.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)

304420

Protocol serial number
IRAS 304420

Study information

Scientific Title
Development of an artificial intelligence system for the automated diagnosis of otitis media with effusion in children

Acronym
DAISYDOME

Study objectives
The newly developed Artificial Intelligence (AI) techniques provide an accurate and reliable automated diagnosis of childhood otitis media with effusion (OME).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending, South East Wales Research Ethics Committee

Study design
Two-arm randomized parallel study

Primary study design
Interventional

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Otitis media

Interventions
The study involves a simple, fast, objective, and non-invasive middle ear measurement using a commercialised device called Wideband Absorbance Immittance (WAI) by Interacoustics after the patient completed their routine hearing assessments. Basically, a small probe will be placed in the patient's ear canal, sending some quiet clicks into their ear, and recording the responses from the ear canal. The WAI test is performed by a clinical researcher and this procedure is very quick (less than 1 minute per test).

The participants will be randomly assigned to two groups that differ according to whether clinicians take the output provided by the AI-WAI support tool into account when making decisions or not:

Group A (diagnostic decision without AI-WAI support tool): clinicians will make their diagnostic decision and subsequent management based on traditional assessments, according to The

National Institute for Clinical Excellence (NICE) guideline for otitis media with effusion in under 12s: surgery (2008). They will not be informed of the test results given by the AI-WAI system.

Group B (diagnostic decision with consideration of AI-WAI output): the clinician will be informed of the outcomes provided by AI-WAI support tool. As a result, they will make the diagnostic decision by considering the AI-WAI support tool.

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
The diagnostic accuracy of the novel AI diagnostic tool compared with routine clinical practice measured at a single timepoint

Key secondary outcome(s))
Energy absorbance of the middle ear measured using the wideband absorbance immittance (WAI) device in different age groups and under various severity conditions in ears with OME at a single timepoint

Completion date
30/09/2022

Eligibility

Key inclusion criteria
Children under 12 years old attending the clinic due to parental concerns regarding hearing loss or for follow-up appointments after acute otitis media

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Upper age limit
12 years

Sex
All

Key exclusion criteria
Children with ventilation tubes in situ

Date of first enrolment

03/01/2022

Date of final enrolment
30/09/2022

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Noah's Ark Children's Hospital for Wales, University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
St David’s Hospital
Child Health Centre
Cowbridge Road East
Canton
Cardiff
United Kingdom
CF11 9XB

Sponsor information

Organisation
Cardiff Metropolitan University

ROR
https://ror.org/00bqvf857

Funder(s)

Funder type
Government

Funder Name
National Institute for Health 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
According to the data storage plan, the collected data will be stored securely on the university's ONEDrive account with password protection, in accordance with the Data Protection Act (1998), the General Data Protection Regulation and Cardiff Metropolitan University's data storage procedures. Access to them will be restricted to the internal research team. The data will be destroyed 5 years after the completion of the project. To protect participant's privacy, no names of participants will be used throughout this research project. The participants' data will be anonymised by the use of a participant reference code on the middle ear measurement data. In regards to data sharing, according to the data policy for publications in professional journals, the data would be made available upon request.

IPD sharing plan summary
Available on request