

Evaluation of a computer aid for assessing stomach symptoms

Submission date 10/06/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 10/06/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/12/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-a-computer-aid-to-help-gps-decide-who-needs-further-tests-for-stomach-symptoms>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

18331

Study information

Scientific Title

Phase II exploratory randomised controlled trial (RCT) comparing use of electronic clinical decision support (eCDS) for suspected oesophago-gastric cancer in primary care with usual care

Acronym

ECASS

Study objectives

The aim of this study is to test the effects of a computerised clinical decision support (eCDS) tool to assist GPs in selection of patients for gastroscopy for possible OG cancer, and to collect all the relevant data to inform a phase III trial of such a tool.

Ethics approval required

Old ethics approval format

Ethics approval(s)

14/NE/1179

Study design

Randomised; Interventional and Observational; Design type: Screening, Qualitative

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Topic: Primary Care; Subtopic: Primary care; Disease: All Diseases

Interventions

Participants are clustered (at the participating site level) to the intervention arm or usual care.

Practices randomised to the intervention arm will be provided with the oesophagogastric (OG) eRAT, which will be embedded into their clinical system. The eRAT provides a dropdown box

containing an interactive risk calculator, which can be opened at the GP's discretion during the consultation. It allows additional symptoms to be entered and generates a value for the risk of a currently undiagnosed OG cancer, together with guidance on whether or not to refer for further investigation.

Intervention Type

Other

Primary outcome measure

Feasibility; Timepoint(s): 6 months

Secondary outcome measures

All measured at six months from patient recruitment, and will be taken from patient notes (primary and secondary care).

1. Practitioner outcomes: frequency and sustainability of use of eRAT, adherence to recommendations, attitudes to and role of eCDS.
2. Service outcomes: referral rates; use of diagnostic pathways (2WW and direct access gastroscopy, conversion (proportion of referrals with cancer diagnosis) and detection rates (proportion of OG cancers referred through these routes); Time from first consultation to diagnosis with cancer (diagnostic interval)
3. Health economic outcomes based on estimates of resource use
4. Patient outcomes: acceptability of use of eCDS

Overall study start date

01/10/2014

Completion date

28/05/2017

Eligibility**Key inclusion criteria**

1. Patients presenting to the GP with symptoms associated with OG cancer (NICE clinical guidelines 17 & 27)
2. Aged 55 years and over
3. Target Gender: Male & Female
4. Aged 55-100

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 3030; UK Sample Size: 3030

Total final enrolment

530

Key exclusion criteria

1. Inability to understand study documentation, for instance because of a lack of English fluency
2. Patients unable to provide informed consent

Date of first enrolment

01/06/2015

Date of final enrolment

28/05/2017

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

NHS North Durham CCG

Durham

United Kingdom

DH1 5TS

Study participating centre

NHS Durham Dales, Easington & Sedgefield CCG

United Kingdom

TS21 3EE

Study participating centre

NHS Darlington CCG

United Kingdom

DL3 6JL

Study participating centre

NHS Hartlepool & Stockton on Tees CCG

United Kingdom

TS23 2LA

Study participating centre
NHS South Tees CCG
United Kingdom
TS3 6AL

Study participating centre
NHS Cambridgeshire and Peterborough CCG
United Kingdom
CB2 8FH

Study participating centre
NHS Bedfordshire CCG
United Kingdom
MK45 4HR

Sponsor information

Organisation
University of Durham (UK)

Sponsor details
Old Elvet
Durham
England
United Kingdom
DH1 3HP

Sponsor type
University/education

ROR
<https://ror.org/01v29qb04>

Funder(s)

Funder type
Government

Funder Name
Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

We intend to report and disseminate the results of the study through peer reviewed scientific journals, internal reporting and newsletters, conference presentations and publications on our websites.

Intention to publish date**Individual participant data (IPD) sharing plan**

Not provided at time of registration

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/04/2016		Yes	No
Results article		18/03/2021	10/05/2021	Yes	No
Plain English results			06/12/2022	No	Yes
HRA research summary			28/06/2023	No	No