Evaluation of a computer aid for assessing stomach symptoms

Submission date	Recruitment status No longer recruiting	Prospectively registered		
10/06/2015		[X] Protocol		
Registration date 10/06/2015	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
06/12/2022	Cancer			

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

Protocol serial number

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

Study type(s)

Treatment

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(s)

Feasibility; Timepoint(s): 6 months

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Αll

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

United Kingdom

England

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)

ROR

https://ror.org/01v29qb04

Funder(s)

Funder type

Government

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Available on request

Study outputs

Output type

Details

Results article		18/03/2021	10/05/2021	Yes	No
<u>Protocol article</u>	protocol	04/04/2016		Yes	No
HRA research summary	Participant information sheet	11/11/2025	28/06/2023		No
Participant information sheet			11/11/2025	No	Yes
Plain English results			06/12/2022	No	Yes