

Diagnosis: Earlier Looking At Your Symptoms - development of a patient-centred tool to measure diagnostic delays

Submission date 30/07/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/09/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/01/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SPON 327-06

Study information

Scientific Title

Diagnosis: Earlier Looking At Your Symptoms - development of a patient-centred tool to measure diagnostic delays

Acronym

DELAYS2

Study objectives

This pilot study aims to determine the acceptability (to patients and research nurses), feasibility and validity of a tool to measure patient and primary delays in cancer. In particular this work will:

1. Pilot the recruitment of patients with a recent and established diagnosis of one of seven specific cancers (or groups of cancers) and the administration of the tool by research nurses
2. Assess non-response bias
3. Assess and seek ways to minimize the level of anxiety that may be raised as part of the data collection process
4. Assess completion rates
5. Compare the response to the tool being administered by a research nurse with self-completion facilitated by a research nurse

Ethics approval required

Old ethics approval format

Ethics approval(s)

North East Wales Local Research Ethics Committee. Date of approval: 03/04/2007 (ref: 07/WNo03/1)

Study design

Multi-centre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Cancer (breast, colorectal, lung, gynaecological, urological, upper GI, haematological)

Interventions

The participants will be randomly allocated to self-completion vs researcher administration of a tool to measure symptoms prior to a diagnosis. The tool is a document with open and closed questions about symptoms patients have had and how long they have had them for.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

To compare the two groups in terms of overall completion rates using an intention to treat analysis

Secondary outcome measures

A comparison will be made between the two modes of the average anxiety levels. This will be assessed after diagnosis as soon as possible, using the Six-item State-Trait Anxiety Inventory (STAI).

Overall study start date

01/09/2008

Completion date

30/09/2009

Eligibility**Key inclusion criteria**

1. Both males and females, age 18+ (no upper limit)
2. Cancer patients with new primary diagnoses of one or groups of the following seven cancers: breast, colorectal, lung, gynaecological, urological, upper gastrointestinal (GI), haematological
3. Patients who are aware of the diagnosis of cancer and confirmed as eligible by Clinical Team

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Key exclusion criteria

1. Patients close to death
2. Patients without mental capacity or linguistic capacity to complete the questionnaire

Date of first enrolment

01/09/2008

Date of final enrolment

30/09/2009

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

North Wales Clinical School

Wrexham

United Kingdom

LL13 7YP

Sponsor information

Organisation

Cardiff University (UK)

Sponsor details

Research and Commercial Division

7th Floor

30-36 Newport Road

Cardiff

Wales

United Kingdom

CF24 0DE

+44 (0)2920 875834

davieskp2@cardiff.ac.uk

Sponsor type

University/education

Website

<http://www.cardiff.ac.uk>

ROR

<https://ror.org/03kk7td41>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (UK) (ref: C8350/A8205)

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

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/01/2014		Yes	No
Plain English results			24/01/2022	No	Yes