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PiPS2: A study investigating predictions about how long patients with advanced cancer have left to live

Submission date 24/06/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [X] Individual participant data
Registration date 28/06/2016	**Overall study status** Completed	
Last Edited 10/07/2023	**Condition category** Cancer	

Plain English summary of protocol
Lay summary under review by external organisation

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16/0057

Study information

Scientific Title
The Prognosis in Palliative care Study II (PiPS2): A multicentre prospective, observational, validation cohort study

Acronym
PiPS2

Study objectives
The overall aim of this research is the validation of models of survival to improve prognostication in advanced cancer care to include the Prognosis in Palliative care Study (PiPS) predictor models.

Primary aim:
To compare PIPS-B prognostic model against clinician predictions of survival and to validate PiPS-A&B prognostic models in palliative care patients with advanced incurable cancer.

Secondary aim:
To validate the PaP, FPN, PPI and PPS prognostic models.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Leeds East Research Ethics Committee, 12/04/2016, ref: 16/YH/0132

Study design
Multi-site prospective cohort validation study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

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
Advanced incurable cancer

Interventions

This study will be investigating prognostic models in patients with advanced incurable cancer. These include the Prognosis in Palliative Care (PiPS) A and B predictor models, the Palliative Prognostic Score (PaP), the Palliative Prognostic Index (PPI), the Feliu Prognostic Nomogram (FPN) and the Palliative Performance Scale (PPS).

In order to calculate the PiPS-A and PPI and PPS score a number of data will be collected. Most of the data can be obtained from scrutiny of the medical notes or discussion with clinical staff. If patients are able to respond to questions (i.e., they are conscious and are not confused) then they will be asked about their symptoms directly, otherwise we will use the assessments of clinical staff as a proxy measure. The data to be collected include information about:
1. Primary diagnosis and sites of metastases (i.e., the places where the cancer has spread). This information will be obtained from a review of the hospital or hospice notes
2. Performance status (i.e., a measure of how "fit" someone is) (4-minute duration)
3. Presence or absence of key symptoms (loss of appetite, weight loss, delirium, difficulty swallowing, breathlessness, fatigue) (5-minute duration)
4. Pulse rate (1-minute duration)
5. Abbreviated mental test score (a test of concentration, attention and memory) (5-minute duration)

Only in those patients who have capacity to consent, a 15mls blood specimen will be collected (Routine haematology and biochemistry, 10-minute duration).

This additional information, when combined with the data described above, will allow for the calculation of the PIPS-B, FPN and the PaP prognostic scores.

Clinician estimates of survival - in order to provide a comparison against which to judge the performance of the prognostic scores we will also ask a doctor and a nurse who are involved in the care of the patient to provide an estimate of how long they think the patient is likely to live. If the doctor and the nurse disagree then we will ask them to confer and to arrive at a consensus. At least three months after the recruitment has ended, a list of study participants (name, date of birth, address and NHS number) will be sent to the Health and Social Information Centre (HSCIC) in order to determine dates of death. From this, we will be able to calculate how long each patient survived and the accuracy of the various prognostic scores and clinician survival estimates.

Intervention Type
Other

Primary outcome measure
1. Survival of the participants are measured from date of study entry
2. Predictions of the PiPS-A and the PiPS-B prognostic models (whether a patient is likely to live for “days” (less than 14-days), “weeks” (2 to 7 weeks), or “months +” (2 months or more))

Secondary outcome measures
Predictions produced by the PPI (less than 3 week survival, 3 to 6 week survival, and greater than 6 week survival); PPS (probability of dying within 7, 14 or 28 days); FPN (risk of dying within 15, 30 or 60 days); PaP (risk of dying within 30 days).

Overall study start date
01/05/2016

Completion date
30/04/2019

Eligibility

Key inclusion criteria
1. Participants with advanced incurable cancer
2. With or without capacity to consent to research
3. Aged 18 years or over
4. Have been recently referred to palliative care services

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1390 approximately

Total final enrolment
1778

Key exclusion criteria
Currently receiving (or planned to receive) treatment with curative intent.

Date of first enrolment
01/07/2016

Date of final enrolment
30/04/2018

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre

Derby Hospital NHS Foundation Trust
Royal Derby Hospital
Uttoxeter New Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Derby Hospital NHS Foundation Trust
Egerton Road
Guildford
United Kingdom
DE22 3NE

Study participating centre
Royal Surrey County Hospital NHS Foundation Trust
Guildford
United Kingdom
GU2 7XX

Study participating centre
St George's Hospital
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre
Nottinghamshire Healthcare NHS Trust
Duncan MacMillan House
Porchester Road
Nottingham
United Kingdom
NG3 6AA

Study participating centre
Leeds Community Healthcare NHS Trust
1 Stockdale House
Headingley Office Park
8 Victoria Road

Leeds
United Kingdom
LS6 1PF

Study participating centre
The Royal Wolverhampton Hospitals NHS Trust
New Cross Hospital
Wolverhampton Road
Wolverhampton
United Kingdom
WV10 0QP

Study participating centre
Worcestershire Royal Hospital
Charles Hastings Way
Worcester
United Kingdom
WR5 1DD

Study participating centre
Cardiff and Vale University Health Board
3, Denbigh House
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Gloucestershire Hospital NHS Trust
1 College Lawn
Cheltenham
United Kingdom
GL53 7AG

Study participating centre
Royal Liverpool and Broadgreen University Hospital NHS Trust
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre
Coventry and Warwickshire Partnership NHS Trust
Wayside House
Wilsons Lane
Coventry
United Kingdom
CV6 6NY

Study participating centre
Central and North West London NHS Foundation Trust
Stevenson House
Hampstead Road
London
United Kingdom
NW1 7QY

Study participating centre
Norfolk Community Health and Care NHS Trust
Elliott House
130 Ber Street
Norwich
United Kingdom
NR1 3FR

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Bronglais General Hospital
Caradog Road
Aberystwyth
United Kingdom
SY23 1ER

Study participating centre

Sussex Community NHS Trust
Brighton General Hospital
Elm Grove
Brighton
United Kingdom
BN2 3EW

Study participating centre
Birmingham St Mary's Hospice
176 Raddlebarn Road
Birmingham
United Kingdom
B29 7DA

Study participating centre
St Giles Hospice
Fisherwick Road
Whittington
Lichfield
United Kingdom
WS14 9LH

Study participating centre
Phyllis Tuckwell Hospice Care
Waverley Lane
Farnham
United Kingdom
GU9 8BL

Study participating centre
Pilgrims Hospices
56 London Road
Canterbury
United Kingdom
CT2 8JA

Study participating centre
St Ann's Hospice
St Ann’s Road North
Heald Green
Brooks Drive

Cheadle
United Kingdom
SK8 3SZ

Study participating centre
Leckhampton Court Hospice
Churchdown
Cheltenham
United Kingdom
GL53 0QJ

Study participating centre
St Richard's Hospice
Wildwood Drive
Worcester
United Kingdom
WR5 2QT

Study participating centre
Martlets Hospice
Wayfield Avenue
Hove
United Kingdom
BN3 7LW

Study participating centre
Marie Curie Hospice Hampstead
11 Lyndhurst Gardens
London
United Kingdom
NW3 5NS

Study participating centre
Princess Alice Hospice
West End Lane
Esher
United Kingdom
KT10 8NA

Study participating centre
St Catherine's Hospice
Malthouse Road
Crawley
United Kingdom
RH10 6BH

Study participating centre
King's College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Marie Curie Hospice
Marsh Lane
Solihull
United Kingdom
B91 2PQ

Study participating centre
Ellenor Hospice
Coldharbour Road
Gravesend
United Kingdom
DA11 7HQ

Study participating centre
St Andrew's Hospice
Peaks Lane
Grimsby
United Kingdom
DN32 9RP

Study participating centre
Douglas Macmillan Hospice
Barlaston Road
Stoke-on-Trent
United Kingdom
ST3 3NZ

Study participating centre
Mary Stevens Hospice
221 Hagley Road
Stourbridge
United Kingdom
DY8 2JR

Study participating centre
Compton Hospice
4 Compton Road West
Wolverhampton
United Kingdom
WV3 9DH

Study participating centre
LOROS Hospice
Groby Road
Leicester
United Kingdom
LE3 9QE

Study participating centre
University Hospitals of Leicester NHS Trust
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Chesterfield Royal Hospital NHS Foundation Trust
Chesterfield Road
Calow
Chesterfield
United Kingdom
S44 5BL

Study participating centre

Nightingale House Hospice
Chester Road
Wrexham
United Kingdom
LL11 2SJ

Study participating centre
St Kentigern Hospice
Upper Denbigh Road
Saint Asaph
United Kingdom
LL17 0RS

Study participating centre
St David's Hospice
Abbey Road
Llandudno
United Kingdom
LL30 2EN

Study participating centre
Frimley Park Hospital
Portsmouth Road
Frimley
United Kingdom
GU16 7UJ

Study participating centre
United Lincolnshire Hospitals NHS Trust
Greetwell Road
Lincoln
United Kingdom
LN2 5QY

Study participating centre
St Barnabas Lincolnshire Hospice
36 Nettleham Road
Lincoln
United Kingdom
LN2 1RE

Sponsor information

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University College London

Sponsor details
1st Floor Maple House
149 Tottenham Court Road
London
England
United Kingdom
W1T 7DN

Sponsor type
University/education

ROR
https://ror.org/02jx3x895

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

Publication and dissemination plan
Presentation of preliminary study results at scientific conferences during the 3 year course of the study and planned publications in high-impact peer reviewed journals around one year after the overall trial end date.

Intention to publish date
30/04/2020

Individual participant data (IPD) sharing plan
Not added at time of registration

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?
Protocol article	protocol	13/08/2018	30/11/2020	Yes	No
Results article		28/04/2021	29/04/2021	Yes	No
Other publications	recruitment analysis	05/05/2021	07/05/2021	Yes	No
Results article		01/05/2021	24/05/2021	Yes	No
Other publications	Secondary analysis of doctors' accuracy	14/04/2022	19/04/2022	Yes	No
HRA research summary			28/06/2023	No	No
Dataset		30/03/2021	10/07/2023	No	No