

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	☒ Prospectively registered ☒ Protocol
Registration date 28/06/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 10/07/2023	Condition category Cancer	☒ Individual participant data

Plain English summary of protocol

Lay summary under review by external organisation

Contact information

Type(s)

Public

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Additional identifiers

Protocol serial number

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

Primary study design

Observational

Study design

Multi-site prospective cohort validation study

Study type(s)

Other

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(s)

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))

Key secondary outcome(s)

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).

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

England

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

Grobby Road
Leicester
United Kingdom
LE3 9QE

Study participating centre

University Hospitals of Leicester NHS Trust

Infirmery 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

Organisation
University College London

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

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