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

Submission date

Recruitment status

No longer recruiting

Registration date Overall s

28/06/2016

Last Edited

24/06/2016

Overall study status

Completed

Condition category

10/07/2023 Cancer

[X] Prospectively registered

[X] Protocol

Statistical analysis plan

[X] Results

[X] Individual participant data

Plain English summary of protocol

Lay summary under review by external organisation

Contact information

Type(s)

Public

Contact name

Dr Anastasia Kalpakidou

Contact details

University College London Maple House 149 Tottenham Court Road London United Kingdom W1T 7NF

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

Study design

Multi-site prospective cohort validation study

Primary study design

Observational

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

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

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 HospiceAbbey 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

Sponsor information

Organisation

LN2 1RE

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		28/04/2021	29/04 /2021	Yes	No
Results article		01/05/2021	24/05 /2021	Yes	No
Protocol article	protocol	13/08/2018	30/11 /2020	Yes	No
<u>Dataset</u>		30/03/2021	10/07 /2023	No	No
HRA research summary			28/06 /2023	No	No
Other publications	recruitment analysis	05/05/2021	07/05 /2021	Yes	No
Other publications	Secondary analysis of doctors' accuracy	14/04/2022	19/04 /2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11 /2025	No	Yes