

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

<b>Submission date</b> 24/06/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 28/06/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/07/2023	<b>Condition category</b> Cancer	<input checked="" type="checkbox"/> 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

**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**

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