

Oral vinorelbine as second-line therapy for patients with malignant pleural mesothelioma

Submission date 16/01/2017	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/01/2017	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 05/10/2022	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-vinorelbine-for-people-with-advanced-pleural-mesothelioma-vim>

Contact information

Type(s)

Public

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT02139904

Clinical Trials Information System (CTIS)

2014-001992-30

Protocol serial number

32185

Study information

Scientific Title

A randomised controlled phase II trial of oral vinorelbine as second line therapy for patients with malignant pleural mesothelioma

Acronym

VIM

Study objectives

The aim of this study is to establish whether treatment with vinorelbine in patients with malignant pleural mesothelioma (MPM) actually makes them live longer.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Wales REC 3, 22/10/2014, ref: 14/WA/1054

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Treatment, Drug

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Specialty: Cancer, Primary sub-specialty: Lung Cancer; UKCRC code/ Disease: Cancer/ Malignant neoplasms of respiratory and intrathoracic organs

Interventions

Participants will be randomised (1:2) to receive either active symptom control (ASC) or ASC with vinorelbine. Participant randomisation will be performed centrally by the WCTU.

Group A: Participants receive active supportive care only for the duration of the study. Active supportive care is defined as the treatments and procedures used locally to control the symptoms of mesothelioma. Examples of symptoms and possible treatments are listed below, but this list is not exhaustive and any supportive treatment may be classed as ASC.

Breathlessness: Chest drain, relaxation, posture advice, medication, anti-anxiety medication, oxygen

Pain Painkillers, relaxation, massage, referral to specialist pain clinics

Night sweats: Management advice, medication

Loss of appetite: High protein powders/high calorie drinks, steroids, nutritional advice, supplements

Tiredness: Sleep advice, gentle exercise

Anaemia: Blood transfusion

Depression: Counselling, anti-depressants

Other: Acupuncture, massage, aromatherapy and relaxation technique

Group B: Patients will be treated with ASC as above, plus vinorelbine. Vinorelbine (Navelbine) should be administered at a dose of 60mg/m² orally weekly for the first cycle (days 1, 8 and 15) on a 3-weekly cycle. Subsequent doses should be increased to 80mg/m² (day 22) if there has been no haematological toxicity. Patients remain on ASC or treatment until disease progression (or unacceptable toxicity or patient withdrawal).

There will be a follow-up assessment at disease progression/End of treatment (Arm B only) and follow-up assessment 30 days after disease progression/End of treatment (Arm B only). Trial follow-up will continue for 18 months after the last participant is randomised.

Intervention Type

Other

Phase

Phase II

Primary outcome(s)

Overall survival will be measured as time from randomisation to death (from any cause).

Key secondary outcome(s)

1. Progression free survival is assessed by modified RECIST using baseline CT scan results compared against further CT scans on Day 1 of each cycle of treatment
2. Safety and tolerability and feasibility of use will be assessed during and after treatment by collection of toxicities according to NCI Common Terminology Criteria for Adverse Events (CTCAE) Version 4.03 at every clinic visit and reporting of SAEs in real-time
3. Objective response rate as assessed by modified RECIST using baseline CT scan results compared against further CT scans on Day 1 of each cycle of treatment

Completion date

01/09/2019

Eligibility

Key inclusion criteria

1. Confirmed histological diagnosis of malignant pleural mesothelioma. The same block or 10 unstained slides should be available for translational research
2. Prior treatment with first-line standard platinum doublet based chemotherapy. Re-challenge with first line chemotherapy is allowed.
3. Evidence of disease progression according to CT scan on Modified RECIST
4. Life expectancy ≥ 3 months
5. ECOG performance status 0-1
6. Men or women aged 18 years or over
7. Willing to consent to provide blood and tissue for translational research
8. Disease which is measurable using modified RECIST
9. Adequate organ function, including the following: Adequate bone marrow reserve: absolute neutrophil count (ANC) $\geq 1.5 \times 10^9/L$, WBC $\geq 3 \times 10^9/L$, haemoglobin $\geq 100g/L$, platelets $\geq 100 \times 10^9/L$; adequate liver function: Bilirubin $< 1.5 \times ULN$ AST/ALT $< 1.5-2.5 \times ULN$.

10. Patients with reproductive potential (male or female), who are sexually active during the duration of the trial or the drug washout period, should be prepared to use two effective forms of contraception throughout their participation in the trial and for at least three months after the last dose of vinorelbine. Effective forms of contraception would include condom with spermicide, along with one of the following: oral contraceptive or hormonal therapy (e.g. hormone implants); placement of an intra-uterine device; vasectomy with assurance of post-vasectomy confirmation of azoospermia; tubal occlusion. Accepted hormonal methods include: Etonogestrel implants; normal and low dose combined oral pills; orelgestromin/ethinyl estradiol transdermal system; or desogestrel.

11. Patients must provide informed consent before any study specific procedures

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Total final enrolment

154

Key exclusion criteria

1. Patients with a diagnosis of a second malignancy except prostate or cervical cancer in remission or patients with a diagnosis of basal cell carcinoma of the skin
2. Have received treatment with an agent that has no marketing authorisation, within 30 days of study entry
3. Are pregnant or breastfeeding. If a participant becomes pregnant during the trial, and is randomised to the treatment arm, vinorelbine must be discontinued and the participant followed up until birth or termination of pregnancy. Breastfeeding must be avoided as it is unknown whether vinorelbine is excreted in human milk.
4. Uncontrolled CNS disease
5. Known contraindication or hypersensitivity to vinorelbine or other vinca alkaloids or to any of the constituents
6. Any disease significantly affecting absorption
7. Previous significant surgical resection of stomach or small bowel
8. Yellow fever vaccine within 30 days of consent
9. Previous vinca alkaloid chemotherapy
10. Palliative radiotherapy within the RECIST area in the 4 weeks prior to baseline CT chest up until randomisation.
11. Patients that are unable to swallow

Date of first enrolment

01/03/2016

Date of final enrolment

31/10/2018

Locations**Countries of recruitment**

United Kingdom

England

Scotland

Wales

Study participating centre**Leicester Royal Infirmary**

Infirmery Square

Leicester

United Kingdom

LE1 5WW

Study participating centre**Velindre NHS Trust**

Velindre Road

Whitchurch

Cardiff

United Kingdom

CF14 2TL

Study participating centre**Churchill Hospital**

Old Road

Headington

Oxford

United Kingdom

OX3 7LE

Study participating centre**Aberdeen Royal Infirmary**

Foresterhill

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United Kingdom
AB25 2ZN

Sponsor information

Organisation

University of Leicester

ROR

<https://ror.org/04h699437>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for the current study are unknown and will be made available at a later date.

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?
HRA research summary			28/06/2023	No	No
Participant information sheet	version V3	15/10/2014		No	Yes
Plain English results			06/04/2022	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes