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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 [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 23/01/2017	**Overall study status** Completed	
Last Edited 05/10/2022	**Condition category** Cancer	

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

Study website
https://www.cardiff.ac.uk/centre-for-trials-research/research/themes/cance

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
2014-001992-30

IRAS number

ClinicalTrials.gov number
NCT02139904

Secondary identifying numbers
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 it 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

Study design
Randomised; Interventional; Design type: Treatment, Drug

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

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

Secondary outcome measures
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

Overall study start date
11/09/2013

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) ≥ 1.5 x 109/L, WBC ≥3 x 109/L, haemoglobin ≥ 100g/L, platelets ≥ 100 x 109/L; adequate liver function: Bilirubin < 1.5 x ULN AST/ALT < 1.5- 2.5 x 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 inter-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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 200; UK Sample Size: 200

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
England

Scotland

United Kingdom

Wales

Study participating centre
Leicester Royal Infirmary
Infirmary 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
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Sponsor information

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/09/2020

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