ISRCTN99131400 https://doi.org/10.1186/ISRCTN99131400

Safety, compliance with and activity of Bezafibrate and medroxyProgesterone acetate (BaP) as non-toxic therapy against myeloid and lymphoid cancers

Submission date
16/09/2011

Recruitment status
No longer recruiting

Registration date
25/10/2011

Overall study status
Completed

Last Edited
11/01/2024

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/trial-looking-new-combination-drugs-some-types-leukaemia-lymphoma

Contact information

Type(s)
Scientific

Contact name
Prof Mark Drayson

Contact details
School of Immunity and Infection
The Medical School
University of Birmingham
Edgbaston
Birmingham
United Kingdom
B15 2TT

Additional identifiers

Clinical Trials Information System (CTIS)
2011-001955-35

Protocol serial number
RG_11-054

Study information

Scientific Title
Single arm phase II trial assessing the safety, compliance with and activity of Bezafibrate and medroxyProgesterone acetate (BaP) as non-toxic therapy against myeloid and lymphoid cancers

Acronym
BaP

Study objectives
To test in patients with acute myeloblastic leukaemia (AML) or high risk myelodysplasia (RAEB2 WHO criteria), B cell Chronic Lymphocytic Leukaemia (CLL) and B cell Non Hodgkins Lymphoma (BNHL) the following outcomes of BaP administration over 18 weeks:
1. Safety
2. Compliance (feasibility of delivery)
3. Anti-cancer activity

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands - Nottingham 2, 13/11/2012, ref: 11/EM/0426

Study design
Phase II single arm four centre pilot study

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Acute Myeloblastic Leukaemia or high risk myelodysplasia (RAEB2 WHO criteria) (AML), B cell Chronic Lymphocytic Leukaemia (CLL) and B cell Non Hodgkins Lymphoma (BNHL)

Interventions
All patients will receive BaP. BaP is Bezafibrate at 6 x 400 mg twice daily and medroxyProgesterone acetate at 5 x 200 mg daily. Patients will commence BaP at registration and continue for 18 weeks where the primary endpoint will be assessed. Patient may continue beyond 18 weeks at the discretion of the treating clinician.

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)

Bezafibrate, Medroxyprogesterone acetate

Primary outcome(s)
1. Safety: The number of grade 3 and 4 Adverse Reactions and Serious Adverse Reactions (SARs) attributable to the trial drugs
2. Patient compliance: Percentage of allocated treatment taken
3. Activity:
3.1. Haematological Response in the first 18 weeks of treatment
3.2. Clinical Response in the first 18 weeks of treatment

Key secondary outcome(s))
Quality of life questionnaires:
1. EQ-5D
2. EORTC QLQ-C30

Measured at baseline, between week 7-11 and at the final assessment at week 18

Completion date
10/09/2014

Eligibility

Key inclusion criteria
1. Patients with one of the following diagnoses:
1.1. AML or high risk myelodysplasia (RAEB-2 WHO criteria)
1.2. CLL
1.3. BNHL
2. Be 18 years or older
3. Have given written informed consent

For AML and MDS
1. Haemopoiesis must be impaired by the disease as judged by an abnormal full blood count (FBC) (International Working Group response criteria in myelodysplasia) and, where there is doubt as to the cause of impaired haemopoiesis, there must be bone marrow aspirate evidence that impaired haemopoiesis is due to cancer involvement of the bone marrow.
2. Abnormal values are haemoglobin level less than 11 g/dL or red blood cells (RBC) transfusion dependence, platelet count less than 100 x 109/L or platelet-transfusion dependence, absolute neutrophil count less than 1.0x 109/L. Pretreatment baseline measures of cytopenias are averages of at least two measurements (not influenced by transfusions, i.e. no RBC transfusions for at least 1 week and no platelet transfusions for at least 3 days) over at least 1 week prior to therapy.

For CLL and BNHL
1. Patients must have either measurable disease (tumour cells in blood at >5 x 109/L, or lymphadenopathy > 1cm) or bone marrow failure due to disease as stated above for MDS / AML.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patient considered suitable for other forms of anti-cancer therapy (either accepted standard therapy or therapy in the context of a clinical trial) other than palliative corticosteroids or hydroxyurea
2. Estimated Glomerular Filtration Rate (eGFR) < 30ml/min
3. Patient known to be allergic to trial drugs
4. Patient has received treatment with any investigational medicinal product within the previous 28 days
5. Patient unable to swallow orally administered medications
6. Patient has uncontrolled seizures
7. Patient has active infection requiring systemic antibiotics, antifungal or antiviral drugs
8. Patient has concurrent severe and/or uncontrolled medical condition [e.g. severe chronic obstructive pulmonary disorder (COPD), severe Parkinsonss disease] or psychiatric condition
9. Women of child-bearing potential and men who have partners of child-bearing potential who are not willing to practise effective contraception for the duration of the study and for three months after the last study drug administration
10. Pregnant or lactating women. Women of child bearing potential must have a negative urine or serum pregnancy test within 7 days prior to registration.

Date of first enrolment
01/10/2012

Date of final enrolment
01/07/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Elizabeth Hospital
Stadium Rd
London
United Kingdom
SE18 4QH

Study participating centre
Heartlands Hospital
Bordesley Green E
Birmingham
United Kingdom
B9 5SS

Study participating centre
Good Hope Hospital
Rectory Rd
Sutton Coldfield
United Kingdom
B75 7RR

Study participating centre
Worcestershire Royal Hospital
Charles Hastings Way
Worcester
United Kingdom
WR5 1DD

Study participating centre
New Cross Hospital
Wednesfield Rd
WV10 0QP
United Kingdom
WV10 0QP

Sponsor information

Organisation
University of Birmingham (UK)

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Queen Elizabeth Hospital Charity (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/04/2019	10/12/2019	Yes	No
HRA research summary			28/06/2023	No	No
Plain English results			11/01/2024	No	Yes