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Phase I study of oral artesunate in colorectal cancer

Submission date 03/12/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/01/2009	**Overall study status** Completed	
Last Edited 27/11/2015	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
07.0195, protocol v2.3 (9 September 2008)

Study information

Scientific Title
Phase I placebo controlled, randomised, double-blind tolerability and efficacy study of oral artesunate in patients with colorectal carcinoma

Study objectives

The primary objective of the study is to determine the anti-cancer effect of oral artesunate in colorectal adenocarcinoma defined as the proportion of malignant cells undergoing apoptosis.

Secondary outcome measures are to establish the tolerability of oral artesunate in colorectal cancer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wandsworth Research Ethics Committee approved on 18th March 2008 (ref: 08/H0803/3)

Primary study design
Interventional

Study design
Single-centre randomised double-blind placebo-controlled interventional study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Colorectal adenocarcinoma

Interventions
Subjects will be randomised to receive 200 mg artesunate or placebo orally once daily for 14 days whilst awaiting surgery for colorectal adenocarcinoma with curative intent.

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
Artesunate

Primary outcome(s)
A significant difference in the proportion of cells that exhibit apoptosis between the two treatment groups (placebo and artesunate), assessed at the time of surgery, after two weeks of drug treatment.

Key secondary outcome(s)
1. Tolerability of artesunate compared with placebo. Tolerability will be assessed according to conventional criteria used in clinical trials, and scored on standardised pro-formas.
2. Comparisons will also be made between baseline haematological and biochemical variables (full blood count, liver function tests, urea and electrolytes), and these measures repeated once treatment stops and before surgery

Assessed after one week and at the end of drug treatment.

Completion date
01/03/2010

Eligibility

Key inclusion criteria
1. Aged 21 - 80 years, male or female
2. With biopsy confirmed single primary site colorectal adenocarcinoma
3. With stages I - IIIb (defined according to conventional criteria)
4. With planned curative resection
5. With written, informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Contraindication to use of artesunate due to hypersensitivity
2. Pregnancy (of any stage)
3. History of hearing or balance problems
4. Immunosuppression or concomitant medication known to interact with artesunate
5. Weight less than 50 kg or greater than 100 kg
6. Severe anaemia (haemoglobin less than 8 g/dl)
7. Other planned intervention, apart from standard of care
8. Inability to give informed consent
9. Inability or unwillingness to take effective contraception in women of child-bearing age
10. Chronic kidney disease of NKF D/QOFI stage 3 or above (estimated glomerular filtration rate [eGFR] less than 60 ml/min)
11. Bilirubin greater than 2 x upper limit of normal in the absence of haemolysis, or known chronic liver disease

Date of first enrolment
01/03/2009

Date of final enrolment
01/03/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Colorectal Surgery
London
United Kingdom
SW17 0RS

Sponsor information

Organisation
St George's, University of London (UK)

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
University/education

Funder Name
St George's, University of London (UK)

Alternative Name(s)
St. George's

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

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	15/11/2014		Yes	No