Phase I study of oral artesunate in colorectal cancer

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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)

Study design

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

Primary study design

Interventional

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

Study participating centre
Department of Colorectal Surgery
London
United Kingdom
SW17 ORS

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 summaryNot 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes