ISRCTN05203252 https://doi.org/10.1186/ISRCTN05203252

# Phase I study of oral artesunate in colorectal cancer

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## 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 measure
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.

### Secondary outcome measures
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.

### Overall study start date
01/03/2009

### 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

### Age group
Adult

### Sex
Both

### Target number of participants
22 subjects

### 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
England

United Kingdom

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

## Sponsor information

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

### Sponsor details
Cranmer Terrace
London
England
United Kingdom
SW17 0RE

### Sponsor type
University/education

### Website
http://www.sgul.ac.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

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**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 |