

# Phase I study of oral artesunate in colorectal cancer

<b>Submission date</b> 03/12/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/01/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/11/2015	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Devinder Kumar

**Contact details**  
Department of Colorectal Surgery  
St George's NHS Healthcare Trust  
Blackshaw Road  
London  
United Kingdom  
SW17 0RS

## 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?
<a href="#">Results article</a>	results	15/11/2014		Yes	No