

# Follow-up to the MOSAIC study (multicentre international study of oxaliplatin/5-fluorouracil /leucovorin in the adjuvant treatment of colon cancer)

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>28/09/2010   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>24/02/2011 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>18/03/2019       | <b>Condition category</b><br>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

Ms Laura Purandare

### Contact details

Oncology Research Unit  
Castle Lane East  
Bournemouth  
United Kingdom  
BH7 7DW  
+44 12 0238 5624  
[Laura.purandare@rbch.nhs.uk](mailto:Laura.purandare@rbch.nhs.uk)

## Additional identifiers

### Protocol serial number

9015

## Study information

**Scientific Title**

A non-interventional follow-up to the MOSAIC study (multicentre international study of oxaliplatin/5-fluorouracil/leucovorin in the adjuvant treatment of colon cancer) up to 10 years and translational research

**Study objectives**

This study will involve analysis of tumours obtained from participants who previously participated in the MOSAIC (NEJM 2004 Jun 3;350(23):2343-51) trial. Prior to MOSAIC, several studies had established that post-operative 5-fluorouracil (5FU) chemotherapy could increase cure rates in colon cancer patients with surgically resectable tumours.

Patients who received the combination of 5FU and oxaliplatin in the MOSAIC trial had superior outcomes, indicating the need for markers which predict which patients may benefit from the addition of oxaliplatin to post-operative therapy. Recruitment to the MOSAIC trial provides a sufficiently large sample of colon cancer patients to enable markers to be evaluated for their association with patient outcome and likelihood of benefit from therapy.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Isle of Wight, Portsmouth and South East Hampshire Research Ethics Committee, 07/05/2009, ref: 09/H0501/30

**Primary study design**

Observational

**Study design**

Observational multicentre non-randomised validation of outcome measures follow-up study

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Topic: National Cancer Research Network; Subtopic: Colorectal Cancer; Disease: Colon, Rectum

**Interventions**

This is a non-interventional study, with a translational element.

**Intervention Type**

Drug

**Phase**

Not Applicable

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

Oxaliplatin, 5-fluorouracil, leucovorin

**Primary outcome(s)**

1. Overall survival defined as the time from first dose of adjuvant therapy until death
2. Disease-free survival defined as local or distant recurrence of colon cancer, second primary colorectal cancer or death of any cause

Primary analysis is scheduled for Q3 2011.

**Key secondary outcome(s)**

1. Time to recurrence-free defined as time to any event related to the same cancer. All same cancer recurrences and deaths from the same cancer are events. Second primary same cancers and other primary cancers are ignored. Death from other cancers, non-cancer-related death, treatment-related death, and lost to follow-up are censored observation.
2. Second cancers
3. Neuropathy (NCI/CTC)
4. Treatment of relapse, i.e. chemotherapy, surgery
5. Molecular markers will be associated with clinical data from the parent MOSAIC clinical study to determine the relationship between presence, absence or relative level of each molecular marker and clinical outcome

**Completion date**

16/03/2012

**Eligibility****Key inclusion criteria**

1. Patients who were enrolled in the MOSAIC study and for whom a representative FPE tumour tissue specimen from their primary tumour is available
2. Male and female, lower age limit of 18 years

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**Key exclusion criteria**

Participants who did not take part in the MOSAIC study

**Date of first enrolment**

16/03/2011

**Date of final enrolment**

16/03/2012

## **Locations**

### **Countries of recruitment**

United Kingdom

England

Australia

Austria

Belgium

Denmark

Finland

France

Germany

Greece

Hungary

Israel

Italy

Netherlands

Norway

Poland

Portugal

Singapore

Spain

Sweden

Switzerland

### **Study participating centre**

**Oncology Research Unit**

Bournemouth

United Kingdom  
BH7 7DW

## Sponsor information

### Organisation

GERCOR (Groupe Coopérateur Multidisciplinaire en Oncologie) (France)

### ROR

<https://ror.org/024w4dn76>

## Funder(s)

### Funder type

Research organisation

### Funder Name

Multidisciplinary Oncology Group Collaboration (Groupe Coopérateur Multidisciplinaire en Oncologie [GERCOR]) (France)

## 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="#">Abstract results</a> | conference abstract | 20/05/2013   |            | No             | No              |
| <a href="#">Study website</a>    | Study website       | 11/11/2025   | 11/11/2025 | No             | Yes             |