

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

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

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
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

Study design

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

Primary study design

Observational

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?
Abstract results	conference abstract	20/05/2013		No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes