ISRCTN38080578 https://doi.org/10.1186/ISRCTN38080578

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

Registration date
24/02/2011

Overall study status
Completed

Last Edited
18/03/2019

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.canceronet.com/gercor_ang/presentation/index.asp

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

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non 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
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 measure
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.

Secondary outcome measures
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

Overall study start date
16/03/2011

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 1000; UK sample size: 264

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
Australia

Austria

Belgium

Denmark

England

Finland

France

Germany

Greece

Hungary

Israel

Italy

Netherlands

Norway

Poland

Portugal

Singapore

Spain

Sweden

Switzerland

United Kingdom

Study participating centre
Oncology Research Unit
Bournemouth
United Kingdom
BH7 7DW

Sponsor information

Organisation
GERCOR (Groupe Coopérateur Multidisciplinaire en Oncologie) (France)

Sponsor details
22 Rue Malher
Paris
France
75004
+33 1 40 29 85 00
Gercor@canceronet.com

Sponsor type
Research organisation

Website
http://www.canceronet.com/

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

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?
Abstract results	conference abstract	20/05/2013		No	No