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First International Randomised trial in Locally Advanced and Metastatic Adrenocortical Cancer Treatment - Etoposide, Doxorubicin, Cisplatin and Mitotane versus Streptozotocin and Mitotane

Submission date 22/08/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 16/09/2005	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 20/08/2008	**Condition category** Cancer	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.firm-act.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CO-ACT-001

Study information

Scientific Title

Acronym
FIRM-ACT

Study objectives
Primary objective of this trial is to investigate whether Etoposide, Doxorubicin, Cisplatin plus Mitotane (EDP-M) as first line treatment will prolong survival as compared to Streptozotocin plus Mitotane (Sz-M) as first line treatment for advanced Adrenocortical Carcinoma (ACC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Adrenocortical Carcinoma

Interventions
Etoposide, Doxorubicin, Cisplatin plus Mitotane (EDP/M) or Streptozotocin plus Mitotane (Sz/M) as first line treatment.

The syudy protocol is available on http://www.firm-act.org/documents/FIRM_ACT_Synopsis.pdf and http://www.firm-act.org/documents/FIRM_ACT_protocol_final.pdf

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Etoposide, Doxorubicin, Cisplatin and Mitotane versus Streptozotocin and Mitotane

Primary outcome measure
Overall survival

Secondary outcome measures
1. Quality of life as measured by EORTC QLQ-C30
2. Time to progression
3. Best overall response rate and duration of response
4. Number of disease-free patients
5. Impact of reaching mitotane blood levels between 14-20 mg/l in both arms on survival and best overall response rate
6. Best overall response rate of both regimens as second line treatment in case of failure of the initial other regime

Overall study start date
01/07/2004

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Histologically confirmed diagnosis of adrenocortical carcinoma
2. Locally advanced or metastatic disease not amenable to radical surgical resection (Stage III-IV)
3. Radiologically monitorable disease
4. Eastern Cooperative Oncology Group (ECOG) performance status zero to two
5. Life expectancy more than three months
6. Age above 18 years
7. Adequate bone marrow reserve (neutrophils more than or equal to 1500/mm^3 and platelets more than or equal to 100,000/mm^3)
8. Effective contraception in pre-menopausal female and male patients
9. Patients written informed consent
10. Ability to comply with the protocol procedures (including availability for follow-up visits)
11. Previous palliative surgery, radiotherapy or radiofrequency ablation is acceptable as long as radiologically monitorable disease is verifiable afterwards.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria
1. History of prior malignancy, except for cured non-melanoma skin cancer, cured in situ cervical carcinoma, or other cancers treated with no evidence of disease for at least five years
2. Previous cytotoxic chemotherapy (prior therapy with mitotane is allowed) for adrenocortical carcinoma
3. Renal insufficiency (serum creatinine more than or equal to 2 mg/dl or creatinine clearance less than or equal to 50 ml/min)
4. Hepatic insufficiency (serum bilirubin more than or equal to two times the institutional upper limit of normal range and/or serum transaminases more than or equal to three times the institutional upper limit of normal range; exception: in patients on mitotane transaminase levels up to five times the institutional upper limit of normal range are acceptable)
5. Pregnancy or breast feeding
6. Known hypersensitivity to any drug included in the treatment protocol
7. Presence of active infection
8. Any other severe clinical condition that in the judgment of the local investigator would place the patient at undue risk or interfere with the study completion
9. Decompensated heart failure (ejection fraction less than 50%), myocardial infarction or revascularization procedure during the last six months, unstable angina pectoris, and uncontrolled cardiac arrhythmia
10. Current treatment with other experimental drugs and/or previous participation in clinical trials with other experimental agents for adrenocortical carcinoma
11. Prisoners

Date of first enrolment
01/07/2004

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Australia

France

Germany

Italy

Netherlands

Sweden

United States of America

Study participating centre
University Hospital Uppsala
Uppsala
Sweden
75185

Sponsor information

Organisation
Collaborative group for Adrenocortical Carcinoma Therapy (CO-ACT) (Germany)

Sponsor details
c/o University Hospital Uppsala (Sweden) and University Hospital Wuerzburg (Germany)
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Sponsor type
Research organisation

Website
http://www.firm-act.org

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Investigator funded trial (CO-ACT)

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