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Combination of Vincristine and Irinotecan with or without Temozolomide (VI or VIT) in children and adults with refractory or relapsed rhabdomyosarcoma

Submission date
22/06/2012

Recruitment status
No longer recruiting

Registration date
22/06/2012

Overall study status
Completed

Last Edited
29/11/2021

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-temozolomide-for-rhabdomyosarcoma

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2010-023135-42

IRAS number

ClinicalTrials.gov number
NCT01355445

Secondary identifying numbers
11903

Study information

Scientific Title
International randomized phase II trial of the combination of Vincristine and Irinotecan with or without Temozolomide (VI or VIT) in children and adults with refractory or relapsed rhabdomyosarcoma

Acronym
VIT-0910

Study objectives
This is an international open-label, multicenter, randomized phase II trial

Primary objective: To evaluate the efficacy of the combination of temozolomide with vincristine and irinotecan in children and adult patients with refractory or relapsed rhabdomyosarcoma as assessed by confirmed objective tumor response

Secondary objective: To evaluate the safety, tolerability and efficacy of VIT and VI alone as assessed by: duration of response, time to tumor progression, time to treatment failure, overall survival and adverse event profile.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central Oxford A, South West REC Centre, 18/01/2012, ref: 11/SC/0410

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
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: Sarcoma; Disease: Soft Tissue

Interventions
Arm A - VI:
Day (D)1 and D8 Vincristine 1.5 mg/m2 (maximum 2mg) direct IV infusion
(0.05 mg/kg for patient ≤ 10 kg)
D1 to D5 Irinotecan 50 mg/m2/d, IV
1 cycle/ 21 days maximum of 12 cycles

Arm B - VIT:
D1 to D5 Temozolomide 125 mg/m2/d, PO*
D1 and D8 Vincristine 1.5 mg/m2 (maximum 2mg) direct IV infusion
(0.05 mg/kg for patient ≤ 10 kg)
D1 to D5 Irinotecan 50 mg/m2/d, IV
1 cycle/ 21 days maximum of 12 cycles
*The dose will be escalated to 150 mg/m2/day at cycle 2 for patients who do not experience > grade 3 toxicity of any kind

Follow Up Length: 60 month(s)

Intervention Type
Drug

Phase
Phase II

Drug/device/biological/vaccine name(s)
Vincristine, irinotecan and temozolomide

Primary outcome measure
Complete or partial tumour response is assessed after the first 2 cycles of treatment which must be confirmed by a follow-up objective tumour assessment.

Secondary outcome measures
1. Duration of response
2. Time to tumour progression
3. Time to treatment failure
4. Overall survival and adverse event profile

Overall study start date
03/02/2011

Completion date
31/12/2021

Eligibility

Key inclusion criteria

Tumor characteristics:
1. Histologically or cytologically confirmed diagnosis of rhabdomyosarcoma (new biopsy recommended)
2. Relapsed or refractory disease which has failed standard treatment approaches
3. Patients must have measurable disease defined as lesions that can be measured in three dimensions by medical imaging techniques such as computerised tomography (CT) or magnetic resonance imaging (MRI). Ascites, pleural fluid, bone marrow disease and lesions seen on Tc scintigraphy or positron emission tomography (PET) scan only are not considered measurable.

Patient characteristics:
1. Age > 6 months and < 50 years
2. Karnofsky performance status (PS) 70-100% (for patients > 12 years of age)
OR Lansky Play Score 70-100% (for patients = 12 years of age)
3. Life expectancy >= 12 weeks
4. Adequate bone marrow function :
4.1. Absolute neutrophil count >= 1000/mm3
4.2. Platelet count >= 100,000/mm3 (transfusion independent)
4.3. Hemoglobin >= 8.5 g/dL (transfusion allowed)
5. Adequate renal function
5.1. Serum creatinine < 1.5 X ULN for age
5.2. If serum creatinine > 1.5 ULN, creatinine clearance or radioisotope GFR) must be > 70 ml/min /1.73 m²
6. Adequate hepatic function :
6.1. Total bilirubin = 1.5 times upper limit of normal (ULN) for age, except if the patient is known to have Gilberts syndrome
6.2. ALT and AST < 2.5 X ULN for age
7. Negative pregnancy test in females with childbearing potential
8. Fertile patients must use effective contraception
9. No active > grade 2 diarrhea or uncontrolled infection
10. No other malignancy, including secondary malignancy
11. Patient affiliated with a health insurance system. Applicable for French patients only
12. Written informed consent of patient and/or parents/ guardians

Prior or concurrent therapy:
1. More than 3 weeks since prior radiation therapy to the site of any progressive lesion that will be identified as a target lesion to measure tumor response
2. At least 3 weeks since prior myelosuppressive therapy (6 weeks for nitrosourea, 2 weeks for vincristine, vinorelbine, vinblastine and lowdose cyclophosphamide)
3. No concurrent enzyme-inducing anticonvulsants (EIAC), including phenytoin, phenobarbital, or carbamazepine
4. No concurrent administration of any of the following : rifampicin, voriconazole, itraconazole, ketoconazole, aprepitant
5. No prior irinotecan or temozolomide administration
6. Prior administration of vincristine is allowed
7. Concurrent palliative radiation therapy to sites allowed except for the main measurable target lesion
8. Prior allo- or autologous SCT allowed; Upper Age Limit 50 years ; Lower Age Limit 6 months

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 80; UK Sample Size: 20

Key exclusion criteria
1. Inclusion criteria failure
2. Concomitant anticancer treatment
3. Know hypersensitivity to any component of study drugs or ingredients
4. Pregnancy or breast feeding
5. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption
6. Neuromuscular disorders (e.g. Charcot-Marie Tooth disease)
7. Uncontrolled intercurrent illness or active infection
8. Unavailable for medical follow-up (geographic, social or mental reasons)

Date of first enrolment
09/02/2012

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
England

France

Italy

Netherlands

Spain

United Kingdom

Study participating centre
School of Cancer Sciences
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
Centre Oscar Lambret (France)

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Sponsor type
Government

ROR
https://ror.org/03xfq7a50

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan

The results of the trial will be published in a peer reviewed scientific journal. At the end of the study, a report will be written by the sponsor, and then validated by the coordinating investigator (Dr. AS Defachelles) of trial VIT-0910. No publication or presentation of the results of this trial will be done without the permission of the sponsor.

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results	Cancer Research UK lay summary of results	23/11/2021	29/11/2021	No	Yes
HRA research summary			28/06/2023	No	No