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An overarching study for children and adults with frontline and relapsed rhabdomyosarcoma

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Registration date 11/06/2019	**Overall study status** Ongoing	
Last Edited 06/08/2025	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-of-treatment-for-children-and-adults-with-rhabdomyosarcoma-far-rms

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Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT04625907

Clinical Trials Information System (CTIS)
2018-000515-24

Protocol serial number

42490

Study information

Scientific Title
FaR-RMS: An overarching study for children and adults with Frontline and Relapsed RhabdoMyoSarcoma

Acronym
FaR-RMS

Study objectives
FaR-RMS is an over-arching study for children and adults with newly diagnosed and relapsed rhabdomyosarcoma (RMS). It is a multi-arm, multi-stage format, involving several different trial questions. FaR-RMS is intended to be a rolling programme of research with new treatment arms being introduced dependant on emerging data and innovation. This study has multiple aims. It aims to evaluate the impact of new agent regimens in both newly diagnosed and relapsed RMS; whether changing the duration of maintenance therapy affects outcome; and whether changes to dose, extent (in metastatic disease) and timing of radiotherapy improve outcome and quality of life. In addition the study will evaluate risk stratification through the use of PAX-FOXO1 fusion gene status instead of histological subtyping and explore the use of FDG PET-CT response assessment as a prognostic biomarker for outcome following induction chemotherapy.
Newly diagnosed patients should, where possible, be entered into the FaR-RMS study at the time of first diagnosis prior to receiving any chemotherapy. However, patients can enter at the point of radiotherapy or maintenance, and those with relapsed disease can enter the study even if not previously entered at initial diagnosis. Patients may be entered into more than one randomisation/registration, dependant on patient risk group and disease status.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval 16/07/2019, North East – Newcastle & North Tyneside 1 Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; Tel: +44 (0)207 1048084; Email: nrescommittee.northeast-newcastleandnorthtyneside1@nhs.net), REC Ref: 19/NE/0145

Primary study design
Interventional

Study design
Randomized; Interventional; Design type: Treatment, Radiotherapy

Study type(s)
Treatment

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

Interventions

FaR-RMS is an over-arching international study for patients with newly diagnosed and relapsed RMS including multiarm, multi-stage questions involving chemotherapy and radiotherapy, with no upper age limit.

Study Entry
FaR-RMS includes a study entry point where all patients with RMS may give consent for the analysis of their biological samples and tumour pathology, alongside the collection of very basic patient characteristics, a treatment summary, and follow-up data for events.

Risk Group Allocation
Patient disease status and risk group allocation will determine which randomisations they are eligible to enter. The risk group assignment is based on analyses performed on outcome data from the recent EpSSG-RMS2005 trial.

Treatment Questions (randomisation/Phase 1b registration)
Patients may be entered into more than one treatment questions following study entry dependent on their disease status. Treatment questions may be available for patients with VHR, HR and Standard Risk (SR) disease. Separate consent is required for study entry and for each trial question. Newly diagnosed patients should, where possible, be entered into the FaR-RMS study at the time of initial diagnosis prior to receiving any chemotherapy. However, newly diagnosed patients can enter at the point of radiotherapy or maintenance, and those with relapsed disease can enter the study at the point of relapse even if not previously entered at initial diagnosis.

Consent
For patients who appear to meet the criteria for participation in the study they and their parents /guardian (if applicable) will be approached by a Consultant or a delegated member of the research team working on this study. This trial will be explained to them and they will be given a copy of the age-specific Patient/Parent Information Sheets to read. The risks, benefits and alternatives to participating in this trial will be made clear to the patient/parent/guardian and they will be told that their participation is entirely voluntary and non-participation will not affect the care they subsequently receive from their medical team. If the patient/parent/guardian is satisfied with the information given and has had the
chance to discuss the study with both the research team and their family and friends, they will be asked to sign a consent form for the study if they wish to participate.
Age appropriate Information Sheets are available and there is a section on the Parent informed Consent Form where patients can document their assent if they wish to do so. For children who are not able to read, write or understand assent, the clinician will explain the trial in an age-appropriate manner and if verbal assent is given by the child it will
be documented in the patient's medical records. Patients should be re-consented at the age of majority in accordance with national guidance/legislation.

Screening assessments
A histologically confirmed diagnosis of RMS is required for Study Entry. It is strongly encouraged for molecular diagnostic results to be obtained prior to study entry to allow for a patient to be assigned to the correct risk group. The diagnosis and RMS subtyping will be performed by the local pathologist, although should this not be possible, the
sample can be sent to the National Pathology Coordinator for an urgent review. For all patients, a formalin fixed paraffin embedded block together with a pseudo- anonymised Pathology report, if available, and molecular results, if available, will be sent to the National Pathology Coordinator as soon as possible after diagnosis for a retrospective

review. The majority of screening assessments are standard of care, and will include blood tests, urine tests, physical exam, and tests to assess disease status: bone marrow examination, a lumbar puncture, scans (e.g. CT, MRI, PET-CT).

Phase 1b dose-finding study:
This will be the first part of the study to open for newly diagnosed patients. The phase 1b irinotecan dose-finding study will investigate the addition of irinotecan to IVA (ifosfamide, vincristine and actinomycin D) chemotherapy (IrIVA). Up to 9 cycles in total will be given to each patient if tolerated. Dose-limiting toxicities (DLTs) will be assessed in Cycles 1 and 2. In the event that a patient experiences a DLT in cycle 1 or cycle 2, irinotecan will be stopped and the patient will continue with IVA as the standard of care. The Data Monitoring
Committee (DMC) will meet after each cohort has been recruited and DLTs assessed to ensure the ongoing safety of the trial.

Induction chemotherapy for newly diagnosed patients:
Once the recommended phase II dose has been established, CT1A and CT1B randomisations will open. CT1A is for newly diagnosed VHR patients, and CT1B is for HR patients. The first 6 patients > 18 years randomised to IrIVA (from either CT1B or CT1A) will be carefully evaluated by the DMC before continuing the randomisation in adult patients to
enhance the oversight of adult patients. In the CT1A randomisation, patients will be randomised to receive either IVADo (Ifosfamide, Vincristine, Actinomycin D,
Doxorubicin) or IrIVA; in CT1B, they will be randomised to IVA or IrIVA. Cycles of chemotherapy will be given at 21-day intervals.

Radiotherapy for newly diagnosed disease:
This trial also contains several radiotherapy randomisations for patients with newly diagnosed RMS.
For patients with resectable disease (disease that can be removed by surgery), there is an RT1A randomisation in which patients will receive radiotherapy either before or after surgery. For those at a higher risk of local failure, they are then eligible to enter a second randomisation, RT1B, in which they will be randomised to receive either 41.4 Gy (standard of care dose) or 50.4 Gy (dose escalated radiotherapy).
For those with non-resectable disease and an incomplete response who are also at a higher risk of local failure, there is also a radiotherapy dose randomization, RT1C, in which the patient will be randomised to receive either to 50.4 Gy (standard of care dose) or 59.4 Gy (dose escalated dose).
For those with unfavourable metastatic disease there is the RT2 randomisation in which the patient will be randomised to either receive radiotherapy treatment to all sites of disease including metastatic sites, or radiotherapy treatment to the primary site and involved regional lymph nodes alone. For both this randomisation and the RT1A
randomisation, patients will be asked to complete a Health-Related Quality of Life questionnaire.
All sites and patients participating in the radiotherapy questions will participate in the Radiotherapy Quality Assurance programme, facilitated via the SIOPE QUARTET (Quality and Excellence in Radiotherapy and Imaging for Children and Adolescents with Cancer across Europe in Clinical Trials) initiative. All sites will be required to be approved for
radiotherapy delivery via QUARTET, and radiotherapy plans for each individual patient will be uploaded to the online system for approval. There will also be a retrospective Quality Control review of all scans and cross-sectional imaging received as part of the radiotherapy QA review process.

Maintenance Chemotherapy:
VHR patients will receive 12 cycles of maintenance chemotherapy as standard of care; HR

patients receive 6 cycles. VHR patients may then be eligible for the CT2A randomisation in which they will either stop treatment or receive 12 further cycles of maintenance chemotherapy, and HR patients for the CT2A randomisation where they will stop or
receive an additional 6 cycles. The chemotherapy for both randomisations is vinorelbine and cyclosphosphamide (VnC) and the cycles are each 28 days. Vinorelbine can be given in either an intravenous or oral format.

Chemotherapy for patients with relapsed disease:
Patients with relapsed disease will be randomised to receive either VIr (Vincristine, Irinotecan) or VIrT (Vincristine, Irinotecan, Temozolomide). Cycles of chemotherapy will be given at 21-day intervals and up to 12 cycles will be given.

FDG PET-CT sub-study:
This study will also encourage an FDG PET-CT or FDG PET-MRI scan after 3 courses of induction chemotherapy to determine prospectively its prognostic value. Should this not be standard of care, the patient will be asked to consent in the optional sub-study.

Follow-up:
Following completion of treatment, the frequency of follow-up assessments should be as per local practice. However, every 3 months for the first 3 years and every 6 months thereafter is suggested. Patients will be followed-up for a minimum of 3 years, until the last patient has been followed-up for 3 years.

Rolling design:
FaR-RMS has been designed to be a rolling programme of research, new treatment arms will be introduced dependant on emerging data and innovation, provided it is within the pre-defined research remit of the trial. A maximum of three new arms will be added to each of the frontline (VHR and HR) and relapse randomisations; and a
maximum of four new arms to the Phase 1b component.

Intervention Type
Mixed

Primary outcome(s)
1. Event-free survival (EFS) – primary outcome measure for CT1A, CT1B, CT2A, CT2B, RT2, CT3. Time is measured as time from each registration/randomisation to first failure event (Relapse or progression of existing disease/occurrence of disease at new sites, death from any cause without disease progression, second malignant neoplasm) or time to last follow-up date if no events
2. Local failure free survival (LFFS) – primary outcome measure for RT1A, RT1B, RT1C, PET Substudy. Defined as time from randomisation to first local failure event (relapse or progression of tumour at the primary site at any time even if there has been a prior concurrent local, regional or distant failure), or time to last follow-up date if no events.

Key secondary outcome(s)
1. Event-free survival (EFS) – secondary outcome measure for RT1A, RT1B, RT1C, All patients, PET Substudy. Time is measured as time from each registration/randomisation to first failure event (Relapse or progression of existing disease/ occurrence of disease at new sites, Death from any cause without disease progression, Second malignant neoplasm) or time to last follow-up date if no events.
2. Overall survival (OS) – secondary outcome measure for CT1A, CT1B, CT2A, CT2B, RT1A, RT1B,

RT1C, RT2, CT3, All patients. Time is measured as time from each registration/randomisation to death from any cause, or time to last follow-up date if no death.
3. Loco-regional failure-free survival (LRFFS) – secondary outcome measure for RT1A, RT1B, RT1C, RT2. Defined as time from randomisation to first local or regional failure event. (relapse or progression of tumour at the primary site at any time even if there has been a prior concurrent local, regional or distant failure or relapse or progression of tumour at regional lymph nodes at any time even if there has been a prior distant failure) or time to last follow-up date if no events.
4. Toxicity – secondary outcome measure for CT1A, CT1B, CT2A, CT2B, Phase 1b, CT3. Measured using Common Terminology Criteria for Adverse Events (CTCAE v 4). Toxicity is measured during cycles 1,2,3,4,5,6,7,8 and 9 of frontline chemotherapy and phase 1b, cycles 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23 and 24 of those randomised to receive additional cycles in CT2A, and cycles 7,8,9,10,11 and 12 of those randomised to receive additional cycles in CT2B.
5. Acute wound complications and post-operative complications – secondary outcome measure for RT1A, RT1B. Measured using specific grade 3 and above complications according to CTCAE v 4 and Clavien Dindo scale from day of surgery to 120 days post surgery. This information is collected 120 days post surgery
6. Acute post-radiotherapy complications – secondary outcome measure for RT1A, RT1B, RT1C, RT2. Measured using any grade 3 and above event according to CTCAE v 4 from completion of radiotherapy to 120 days post completion of radiotherapy. This information is collected 120 days post completion of radiotherapy.
7. Late local therapy complications – secondary outcome measure for RT1A, RT1B, RT1C. Measured using specific grade 3 and above events according to CTCAE and Clavien-Dindo scale from 120 days from date of last local therapy until end of follow up (minimum three years). Follow up is as per local practise, but we are likely to collect this information at follow up year 1,2,3 and then as many years afterwards as they wish to supply.
8. Health-related quality of life (HRQoL) – secondary outcome measure for RT1A, RT2. Assessed using PedsQL for the paediatric population (under 18 years) and EORTC QLQ-C30 for patients 18 years of age and over. This will be assessed for eligible patients at the following timepoints: at the start of radiotherapy, at completion of radiotherapy, 3 months following the end of radiotherapy, 24 months following radiotherapy.
9. Response (R) – secondary outcome measure for Phase 1b, CT1A, CT1B, CT3. Defined as complete (CR) or partial response (PR) and is clinically defined. Patients who are not assessable for response – e.g. because of early stopping of treatment or death – will be assumed to be non-responders. Response will be assessed after course 2 and 6 for the newly diagnosed chemotherapy for very high risk and high risk randomisations; it will be assessed after course 2 and 4 for the relapse randomisation.
10. Duration of response – secondary outcome measure for CT3. Defined as time from the date of first response (as defined above) to date of relapse, progression or death from any cause.
11. Best response (BR) – secondary outcome measure for CT3. Assessed throughout the treatment for the relapse randomisation.
12. Recommended phase 2 dose (RP2D) – secondary outcome measure for Phase 1b. Based on tolerability, where tolerability is evaluated through the occurrence of dose-limiting toxicity (DLT). DLTs will be defined in the relevant protocol section for each Phase Ib study. DLTs are collected up to 21 days after the start of cycle 2 for Phase 1b.
13. Maximum tolerated dose (MTD) – secondary outcome measure for Phase 1b. Defined as the dose level at which no or one participant experiences a DLT when at least two of three to six participants experience a DLT at the next highest dose. DLTs are collected up to 21 days after the start of cycle 2 for Phase 1b.
14. PET response – secondary outcome measure for Phase 1b. Assessed by PERCIST criteria after 3 cycles of chemotherapy.

Completion date

01/03/2030

Eligibility

Key inclusion criteria

Inclusion criteria for study entry:
1. Histologically confirmed diagnosis of RMS (except pleomorphic RMS)
2. Written informed consent from the patient and/or the parent/legal guardian

Inclusion criteria for all randomisations and registrations:
1. Patient agrees to use contraception during therapy and for 12 months after last trial treatment (females) or 6 months after last trial treatment (males), where patient is sexually active
2. Written informed consent from the patient and/or the parent/legal guardian
3. Medically fit to receive treatment

Frontline chemotherapy specific inclusion:
1. Entered into the FaR-RMS study at diagnosis
2. No prior treatment for RMS other than surgery
3. Documented negative pregnancy test for female patients of childbearing potential
4. Adequate hepatic function: Total bilirubin ≤ 1.5 times upper limit of normal (ULN) for age, unless the patient is known to have Gilbert's syndrome

Phase 1b specific inclusion:
1. VHR disease
2. Age >12 months and ≤25 years
3. Adequate hepatic function: ALT or AST < 2.5 X ULN for age
4. Adequate renal function: estimated or measured creatinine clearance ≥60 ml/min/1.73 m2
5. Absolute neutrophil count ≥1.0x 10^9/L
6. Platelets ≥ 80 x 10^9/L

CT1a specific inclusion:
1. VHR disease
2. Age ≥ 6 months
3. Available for randomisation ≤60 days after diagnostic biopsy/surgery
4. Fractional Shortening ≥ 28%
5. Absolute neutrophil count ≥1.0x 10^9/L (except in patients with documented bone marrow disease)
6. Platelets ≥ 80 x 109/L (except in patients with documented bone marrow disease)

CT1b specific inclusion:
1. HR disease
2. Age ≥ 6 months
3. Available for randomisation ≤60 days after diagnostic biopsy/surgery
4. Absolute neutrophil count ≥1.0x 10^9/L
5. Platelets ≥ 80 x 10^9/L

Radiotherapy inclusion:
1. Entered into the FaR-RMS study (at diagnosis or prior to radiotherapy randomisation)
2. VHR, HR and SR disease
3. ≥ 2 years of age

4. Receiving frontline induction treatment as part of the FaR-RMS trial or with a IVA/IVADo based chemotherapy regimen. Note that patients for whom ifosfamide has been replaced with cyclophosphamide will be eligible
5. Documented negative pregnancy test for female patients of childbearing potential

RT1a and RT1b specific inclusion:
1. Primary tumour deemed resectable (predicted R0/ R1 resection feasible) after 3 cycles of induction chemotherapy (6 cycles for metastatic disease)
2. Adjuvant radiotherapy required in addition to surgical resection (local decision)
3. Available for randomisation after cycle 3 and prior to the start of cycle 6 of induction chemotherapy for localised disease, or after cycle 6 and prior to the start of cycle 9 for metastatic disease

RT1b and RT1c specific inclusion:
1. Higher Local Failure Risk (HLFR) based on presence of either of the following criteria:
2. Unfavourable site
3. Age ≥ 18yrs

RT1c specific inclusion:
1. Primary radiotherapy indicated (local decision)
2. Available for randomisation after cycle 3 and prior to the start of cycle 6 of induction chemotherapy for localised disease, or after cycle 6 and prior to the start of cycle 9 for metastatic disease

RT2 specific inclusion:
1. Available for randomisation after cycle 6 and before the start of cycle 9 of induction chemotherapy
2. Unfavourable metastatic disease, defined as Modified Oberlin Prognostic Score 2-4

Maintenance specific Inclusion:
1. Received frontline induction chemotherapy as part of the FaR-RMS trial or with a IVA/IVADo based chemotherapy regimen
2. Patients for whom ifosfamide has been replaced with cyclophosphamide will be eligible
3. No evidence of progressive disease
4. Absence of severe vincristine neuropathy – i.e requiring discontinuation of vincristine treatment)

CT2a specific inclusion:
1. VHR disease
2. Completed 11 cycles of VnC maintenance treatment (either oral or IV regimens)

CT2b specific inclusion:
1. HR disease
2. Completed 5 cycles of VnC maintenance treatment

Relapse CT3 specific inclusion:
1. Entered into the FaR-RMS study (at diagnosis or at any subsequent time point including at relapse)
2. Age ≥ 6 months
3. First or subsequent relapse of RMS

4. No cytotoxic chemotherapy or other investigational medicinal product (IMP) within previous two weeks
5. Documented negative pregnancy test for female patients of childbearing potential

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria
Phase 1b specific exclusion:
1. Weight <10kg
2. Active > grade 2 diarrhoea
3. Prior allo- or autologous Stem Cell Transplant
4. Uncontrolled inter-current illness or active infection
5. Pre-existing medical condition precluding treatment
6. Known hypersensitivity to any of the treatments or excipients
7. Second malignancy
8. Pregnant or breastfeeding women
9. Urinary outflow obstruction that cannot be relieved prior to starting treatment
10. Active inflammation of the urinary bladder (cystitis)

CT1a and CT1b specific exclusion:
1. Active > grade 2 diarrhoea
2. Prior allo- or autologous Stem Cell Transplant
3. Uncontrolled inter-current illness or active infection
4. Pre-existing medical condition precluding treatment
5. Known hypersensitivity to any of the treatments or excipients
6. Second malignancy
7. Pregnant or breastfeeding women
8. Urinary outflow obstruction that cannot be relieved prior to starting treatment
9. Active inflammation of the urinary bladder (cystitis)

Radiotherapy specific exclusion
1. Prior allo- or autologous Stem Cell Transplant
2. Second malignancy
3. Pregnant or breastfeeding women
4. Receiving radiotherapy as brachytherapy

CT2a and CT2b specific exclusion:
1. Prior allo- or autologous Stem Cell Transplant
2. Uncontrolled inter current illness or active infection
3. Second malignancy
4. Pregnant or breastfeeding women

5. Urinary outflow obstruction that cannot be relieved prior to starting treatment
6. Active inflammation of the urinary bladder (cystitis)

CT3 specific exclusion:
1. Active > grade 2 diarrhoea
2. Prior allo- or autologous Stem Cell Transplant
3. Uncontrolled inter-current illness or active infection
4. Pre-existing medical condition precluding treatment
5. Known hypersensitivity to any of the treatments or excipients
6. Second malignancy
7. Pregnant or breastfeeding women

Date of first enrolment
31/07/2020

Date of final enrolment
31/08/2026

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

Scotland

Wales

Australia

Austria

Belgium

Canada

Czech Republic

Denmark

Finland

France

Germany

Greece

Ireland

Israel

Italy

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New Zealand

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Slovenia

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Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK; Grant Codes: C18599/A22043

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

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 2.0	21/03/2024	19/06/2024	No	No