Research Article

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Supplementary Text

Synopsis

Study Title: DOUBLE-SKIN: a New Approach in Laser Surgery Using the Regenerative Solution in Children Diagnosed with Vascular Anomaly.

Study Design: A Randomised, Double-blind, Placebo-controlled Trial.

Study Participants: Children (≤18 years old) with clinically diagnosed Vascular pathology admitted to the Vascular Anomalies Centre.

Key Inclusion Criteria:

• clinically diagnosed Vascular Pathology

Key Exclusion Criteria:

- Age
- Severe allergic reaction
- Related syndromes
- Planned Sample Size: 300
- Planned Study Period: a year

Intervention:

If a laser surgery is required the patient will be randomised 1:1 to either:

"Intervention" arm or "Control" arm. Patients who do not require a laser surgery under the general anesthesia will be invited to participate in an observational cohort study. Main outcome measures and endpoints are presented in Appendix A.

- Recruitment
- Informed Consent
- Screening and Eligibility Assessment
- Co-enrolment Guidelines
- Randomization, blinding and code-breaking

Once written consent is obtained and the patient has been randomised, the patient will be assigned a unique patient trial number that will then be used on the baseline e-CRF (including basic demographic data) and for all subsequent e-CRFs.

Study Assessments

Collection of Baseline Clinical Data (All Patients)

This includes demographics, details of clinical history and past medical history, symptoms, drug history, smoking (tobacco and marijuana) history, morphometric data (height and weight) and baseline clinical observations (heart rate, respiratory rate, oxygen requirement, blood pressure), as recorded in normal clinical care.

Daily Clinical Data (Intervention and Control Arm Only)

In addition to a daily CXR, whilst an in-patient, all patients will have baseline clinical observations (heart rate, respiratory rate, oxygen requirement, blood pressure), recorded on the e-CRF.

Questionnaires and VAS (Visual Analogue Scale) Assessment

All patients will be asked to complete the EQ-5D-5L questionnaire (at baseline/on the day of admission and then at 1 week post completion of treatment and at 1, 6 and 12 month post enrolment) and the Visual Analogue Scale assessment to measure thoracic pain and breathlessness (at baseline, daily with device/drain in situ and at follow-up – as above). These will be completed by patients on paper CRFs and originals posted to ORTU for scoring and data entry.

Follow-up Visits (All patients)

1-week post initial presentation to hospital (observational cohort)* or completion of treatment (randomised group) follow-up visit (+/- 1 day)

- CRF completion, review of patient resource diaries, quality of life assessments 1-month post initial presentation to hospital (observational cohort) or randomisation (randomised group) follow-up visit (not less than 30 days /+ 1 week)

- CRF completion, review of patient resource diaries, quality of life assessments. Failure to attend follow up

All patients will have out-patient follow-up at 1 week post completion of treatment (+/- 1 day), 1 month (+/- 1 week), 6 months (+/- 1 week) and 12 months (+/- 1 month) post enrolment to assess recurrence rate. Patients might receive text message reminders for their follow-up appointments. However, in exceptional circumstances, patients not able to attend the follow-up outcome point will be contacted by phone to at least check their status. If this is not possible as much data as possible should be collected through medical notes.

Withdrawal of Participants from Study

In consenting to the study, patients are consenting to treatment according to the study protocol, follow- up and data collection. If a patient wishes to withdraw from the study, the investigator should nevertheless explain the importance of remaining in follow-up or failing this of allowing routine follow- up data to be used for study purposes. If the patient explicitly states their wish not to contribute further data to the study, the patient should be withdrawn, the investigator should complete the withdrawal form as part of the e-CRF and the ORTU should be informed in writing. Data collected up to the point of withdrawal can still be included in the study or data collection can continue through medical notes as long as the patient agrees to this.

Definition of End of Study

The study will close at the point when the last patient has completed their last follow-up visit.