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Prevalence and risk factors of hair-loss in survivors of critical illness

Submission date
15/02/2017

Recruitment status
No longer recruiting

Registration date
02/03/2017

Overall study status
Completed

Last Edited
16/08/2022

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Alopecia (hair-loss) in adult survivors of critical illness has received limited attention in critical care research. Hair-loss is of minimal concern to the intensive care team, when patient survival is the primary objective of care given. However, hair-loss can prove distressing for the patient, especially after recovering from a serious illness. In a recent pilot study in Morriston Hospital (UK), it was found that 17% of patients attending the Intensive Care Unit (ICU) follow up clinic, complained of hair-loss. There is very little research about how often hair-loss occurs in survivors of a critical illness. The first objective of the study is to investigate the incidence and nature of hair-loss in adult survivors of critical illness. The second objective is to investigate the risk factors for hair-loss in adult survivors of critical illness.

Who can participate?
Adults over the age of 18 who are in the ICU for five days or more.

What does the study involve?
During participant's ICU stay, data is collected regarding their demographics and about their health variables that are considered a potential risk for alopecia. Three months after participants are discharged, they are sent a survey regarding potential hair loss to complete and return to the research team. If the survey is not returned after one month, participants receive a phone call by the researchers in order to assist them with their survey.

What are the possible benefits and risks of participating?
Participants may benefit from having potential risk factors for hair loss identified. There are no notable risks with participating.

Where is the study run from?
This study is being run from Morriston Hospital (UK) takes place in hospitals in Wales (UK).

When is the study starting and how long is it expected to run for?
August 2016 to December 2017

Who is funding the study?
Abertawe Bro Morgannwg University Health Board (UK)

Who is the main contact?
Dr Ceri Battle
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Contact information

Type(s)
Public

Contact name
Dr Ceri Battle

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 5

Study information

Scientific Title
Alopecia in Survivors of CRitical Illness: a Mixed methods study

Acronym
ASCRIM

Study objectives
The aim of the study is to investigate the prevalence, nature and risk factors for alopecia in survivors of critical illness.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North of Scotland Research Ethics Service, 21/11/2016, ref: 16/NS/0133

Study design
Mixed methods prospective observational epidemiological study

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
Hospital

Study type(s)
Other

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
Alopecia

Interventions
This study consist of two phases. In the first phase, patients are approached to participate in the study. This is done when the patient has been in the Intensive Therapy Unit (ITU) for five or more days and is able to provide written consent. During the patient's ITU stay, data collection is completed by the researcher, which involves collecting details about demographics and variables that are considered potential risk factors for alopecia, taken from the patient's medical records. The researcher records age, sex, admission diagnosis, sepsis, past medical history, blood products transfused during stay, relevant drugs that are known risk factors for alopecia, physiological data and discharge data such as length of stay, mechanical ventilation days, respiratory/cardiovascular/renal support during stay.

The second phase of the study occurs three months post ITU discharge. The patient is sent a survey regarding alopecia to complete. If the patient fails to return the survey after one month, they are followed up with a phone call by the research team to assist with survey completion as required.

Intervention Type
Other

Primary outcome measure
Prevalence and nature of patient reported alopecia in survivors of critical illness is measured using a patient reported survey at three months post ITU discharge.

Secondary outcome measures
Risk factors for alopecia in survivors of critical illness are measured using a patient record survey at three months post ITU discharge.

Overall study start date
01/08/2016

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Aged 18 years or more (no upper limit)
2. Capacity to consent to participation
3. Capacity to complete survey
4. ICU stay of five or more days
5. Survived to three months post ICU discharge

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Aged less than 18 years
2. No capacity to consent to participation
3. No capacity to complete survey
4. ICU stay of less than five days
5. Does not survive to three months post ICU discharge
6. Patients requiring chemotherapy that will potentially cause alopecia
7. Patients who suffer with any pre-existing alopecia / baldness

Date of first enrolment
01/05/2017

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Morriston Hospital
Heol Maes Eglwys
Swansea
United Kingdom
SA6 6NL

Study participating centre
University Hospital Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
Royal Gwent Hospital
Cardiff Road
Newport
United Kingdom
NP20 2UB

Study participating centre
Nevill Hall Hospital
Brecon Road
Abergavenny
United Kingdom
NP7 7EG

Study participating centre
Royal Glamorgan Hospital
Ynysmaerdy
Llantrisant
United Kingdom
CF72 8XR

Study participating centre
Princess of Wales Hospital
Coity Road
Bridgend
United Kingdom
CF31 1RQ

Study participating centre
Prince Charles Hospital
Gurnos Road
Merthyr Tydfil
United Kingdom
CF47 9DT

Study participating centre
Bronglais Hospital
Caradoc Road
Aberystwyth
United Kingdom
SY23 1ER

Study participating centre
Wrexham Maelor Hospital
Croesnewydd Road
Wrexham
United Kingdom
LL13 7TD

Study participating centre
Glan Clwyd Hospital
Rhuddlan Road
Bodelwyddan
United Kingdom
LL18 5UJ

Study participating centre
Ysbyty Gwynedd
Bangor

United Kingdom
LL57 2PW

Study participating centre
Glangwili General Hospital
Dolgwili Road
Carmarthen
United Kingdom
SA31 3AF

Study participating centre
Withybush Hospital
Fishguard Road
Haverfordwest
United Kingdom
SA61 2PZ

Sponsor information

Organisation
Abertawe Bro Morgannwg University Health Board

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04zet5t12

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Abertawe Bro Morgannwg University Health Board

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/06/2018

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?
Results article	results	01/04/2019		Yes	No
Protocol file	version 5.2	18/10/2017	16/08/2022	No	No
HRA research summary			28/06/2023	No	No