Prevalence of alcohol use disorder in patients with skin disease

Submission date 08/08/2012	Recruitment status No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 26/09/2012	Overall study status Completed	 [] Statistical analysis plan [X] Results
Last Edited 21/01/2019	Condition category Mental and Behavioural Disorders	Individual participant data

Plain English summary of protocol

Background and study aims:

At present, apart from documenting the levels of alcohol intake, most dermatology clinics have not attempted to modify the drinking behaviour of patients. During the last 10 years, clinic based programmes have been developed to effectively lower alcohol consumption. These tools could be put to significant benefit in the dermatology clinics.

To deploy a successful programme, data on the drinking behaviour of patients is needed. Firstly we need to identify which groups of dermatology patients need to be targeted. We know that patients with psoriasis often drink heavily, however whether the alcohol is a trigger or a consequence of psychological distress is not known. There is very little information on whether patients with other inflammatory skin disease such as eczema or cutaneous lupus are also heavy drinkers. Rosacea is often thought to be linked to alcohol although good data is lacking. We also do not know whether non inflammatory skin diseases such as skin cancer influence alcohol consumption.

Who can participate?

Patients currently suffering from skin diseases , attending skin disease clinics in Newcastle upon Tyne, UK.

What does the study involve?

Firstly, we will do some preliminary, questionnaire based work in the dermatology clinics to identify which groups of patients are drinking above recommended levels. We will also explore the acceptability of asking about alcohol use in patients in the skin clinics. Data from each group of patients will be compared, to conclude if alcohol use disorders (AUDs) are more prevalent within patients with inflammatory skin disorders. To do this, we will utilise the 10 item one page AUDIT screening questionnaire to identify patients with AUDs. This information will allow the team to gather the necessary information to gauge the prevalence of the issue and work towards putting together a grant to test the effectiveness of brief interventions in this setting.

What are the possible benefits and risks of participating?

There are no immediate benefits for the participating in this study. Participation will be contribute to research which could be of possible future benefit to patients and others in the same circumstances. The analysis of the information gathered will allow a future research study

to provide alcohol screening and a brief programme for patients with skin disease, in a dermatology clinic setting. For some patients, this research may immediately identify their own need for support in regards to their alcohol consumption, stress or anxiety. There are no anticipated risks of participating within this research. However, some patients may feel some minor psychological stress when completing the questionnaires, due to the topic that they address.

Where is the study run from? Royal Victoria Infirmary, Newcastle upon Tyne, UK

When is study starting and how long is it expected to run for? The study is expected to start on 1 October 2012 and is expected to run for 2 years.

Who is funding the study? The British Skin Foundation

Who is the main contact? Dr Phillip Hampton Philip.Hampton@nuth.nhs.uk

Contact information

Type(s) Scientific

Contact name Dr Philip Hampton

Contact details

Royal Victoria Infirmary Department of Dermatology Queen Victoria Road Newcastle Upon Tyne United Kingdom NE1 4LP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 12183

Study information

Scientific Title

Examining the prevalence of alcohol use disorders (AUDs) in patients with skin disease: an observational study

Study objectives

The aim of this study is to to use the 10 item one page Alcohol Use Disorders Identification Test (AUDIT) screening questionnaire to identify patients with AUDs, attending skin disease clinics in Newcastle. The study also aims to ask patients whether, should it be offered, they would be willing to take part in brief clinic based interventions to lower alcohol consumption. This information will enable the team to gather the necessary information to gauge the prevalence of the issue and work towards putting together a grant to test the effectiveness of brief interventions in this setting.

Ethics approval required Old ethics approval format

Ethics approval(s) NRES Committee North East - Sunderland, 25/05/2012, ref: 12/NE/0154

Study design Observational pilot study

Primary study design Observational

Secondary study design Other

Study setting(s) Hospital

Study type(s) Screening

Participant information sheet

Not available in web format, to request patient information sheet please contactMs Bianca TobinResearch OfficeDermatology Outpatient DepartmentLevel 2, New Victoria WingRoyal Victoria Infirmary Queen Victoria RoadNewcastle upon TyneTyne and WearNE1 4LPTel: +44 (0) 191 28 23568

Health condition(s) or problem(s) studied

Alcohol use disorders

Interventions

This study will be a single site study, where patients who are attending the Dermatology outpatient department will be recruited. The full spectrum of skin diseases are seen in a variety of both general and specialised clinics and we aim to recruit approximately 720 patients in a 2 year period. There will be two main groups of patients targeted based on their skin disease diagnoses.

Group 1

We will recruit from the major inflammatory skin diseases psoriasis, eczema, lupus and a group

of miscellaneous other inflammatory skin diseases in the following manner.

1. Psoriasis - 120 patients

2. Eczema - 120 patients

3. LUPUS - 120 patients

4. Other - 120 patients

Group 2

We will sample a reference population of 240 patients with non-inflammatory skin diseases. The reference population group will comprise of any patients with non inflammatory skin problems. This means patients with skin lesions or other structural skin problems where the skin is not inflamed or itchy. We will aim to recruit 240 patients in this group.

As well as collecting demographic data and data relating to the patients skin disease the questionnaire will include the following tools:- AUDIT, Hospital Anxiety and Depression Scale (HADS) and Dermatology Life Quality Index (DLQI).

Intervention Type

Other

Phase Not Applicable

Primary outcome measure

To ascertain the prevalence of alcohol use disorders in a proportion of patients attending the dermatology out patient clinics using the Alcohol use disorders identification test (AUDIT).

Secondary outcome measures

1. To record the dermatology life quality index (DLQI) for each patient

2. To record the hospital anxiety and depression score (HADS) for each patient

Overall study start date

01/10/2012

Completion date

30/11/2014

Eligibility

Key inclusion criteria

Patients will be recruited into one of two groups:

Group1

- 1. A diagnosed inflammatory skin disease made by a dermatologist
- 2. Aged between 18 and 75 years inclusive
- 3. Male or Female
- 4. Able to provide written informed consent

Group2

1. A diagnosed non-inflammatory skin disease made by a dermatologist

2. Aged between 18 and 75 years inclusive

3. Male or Female

4. Ability to provide written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex Both

Target number of participants UK Sample Size: 720

Key exclusion criteria

Patients under the age of 18 years
 Patients who are unable to give written informed consent
 Male & female

Date of first enrolment 01/10/2012

Date of final enrolment 30/11/2014

Locations

Countries of recruitment England

United Kingdom

Study participating centre Royal Victoria Infirmary Newcastle Upon Tyne United Kingdom NE1 4LP

Sponsor information

Organisation Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details Midwifery Research Department Leazes Wing Queen Victoria Road Newcastle upon Tyne England United Kingdom NE1 4LP

Sponsor type Hospital/treatment centre

Website http://www.newcastle-hospitals.org.uk/

ROR https://ror.org/05p40t847

Funder(s)

Funder type Charity

Funder Name British Skin Foundation (UK)

Alternative Name(s) BSF

Funding Body Type Private sector organisation

Funding Body Subtype Trusts, charities, foundations (both public and private)

Location United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	01/09/2017	21/01/2019	Yes	No