Imperial College
London

ASCARA

Multinational Anal Squamous Cell Carcinoma: Registry and Audit

Information for Researchers

IRAS: 335443

Introduction

Anal Squamous Cell Carcinoma (SCC) is an uncommon cancer with an incidence rate between 1 and 2 per 100,000 per year. The incidence of anal SCC is increasing rapidly, with an overall 63% increase in incidence rate of anal SCC in the UK since the 1990's. However, there is much discrepancy in best surgical practice for the treatment and prevention of anal SCC.

As anal SCC is a rare cancer it is difficult to gain sufficient patient numbers with enough statistical power to be able to provide evidence-based conclusions on best practice. Regional guidelines differ considerably and there is widespread variance in practice between different clinical centres.

Although generic cancer databases such as Cancer Outcomes and Services Dataset (COSD) in the UK and the National Cancer Database (NCDB) in the USA exist they are limited to the data streams that are available to them. Both cannot link, for example, to HIV status or outcomes related anal high-grade squamous intraepithelial lesion (HSIL) (the precursor to SCC). Neither can they report treatment regimes and recurrence rates. It is likely that the increasing incidence is related to, at least in part, the increasing prevalence of HIV therefore not including this data is a significant confounding factor.

In order to provide a suitable platform to allow further dedicated study into anal SCC, we have developed an international Anal Squamous Cell Carcinoma registry; mASCARA.

What is mASCARA?

mASCARA is a secure web-based platform that has been available to use from May 2019. It has been designed to be GDPR compliant and has gained ethical approval from a specialist GDPR database Research and Ethics Committee in the UK. Data is pseudoymised to submitting direct care teams (to allow outcomes such as survival and recurrence to be updated by the direct care team over time) but is fully anonymised to the study group.

We are rolling out the platform to clinical centres who wish to include their retrospective and prospective data voluntarily. Our aim however would be, similar to other schemes like the National Bower Cancer Audit in the UK, to gain endorsement from regional Colorectal associations for international mandatory adoption.

Method

We are requesting the submission of retrospective anal SCC or HSIL patients as well as the prospective recruitment of patients with newly diagnosed with anal SCC or HSIL.

Any patient diagnosed with anal SCC/HSIL before 15/01/2024 is defined as a retrospective patient and will not need to be consented to be included in mASCARA.

However, prospective patients will need to give their informed consent prior to their inclusion in mASCARA. A prospective patient is defined as any person diagnosed with anal SCC or HSIL after 15/01/2024. An example consent form and patient information leaflet has been provided within the study documents.

HSIL will be defined as patients with histology specimens classified as:

- AIN2
- AIN3
- Moderate Anal Intraepithelial Neoplasia.
- Severe Anal Intraepithelial Neoplasia
- HSIL (High grade squamous intraepithelial lesion)

Once registered to take part, local Research and information governance approval will need to be completed at the new clinical site please see Figure 1

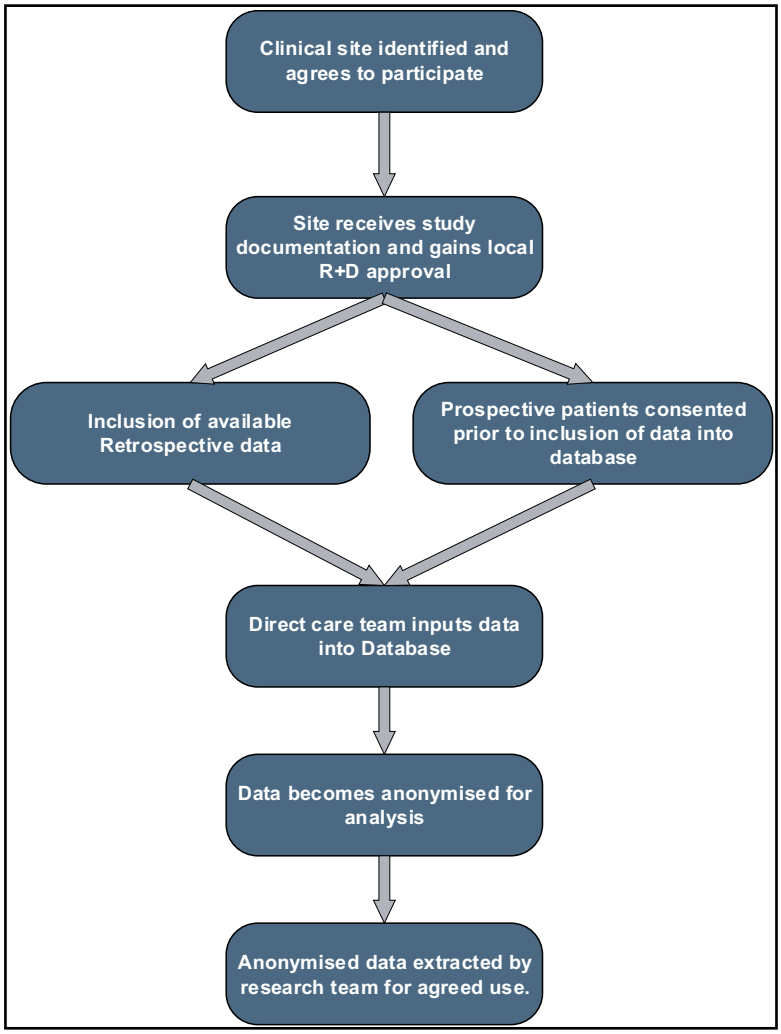

Figure 1: Data flow after identification of participating clinical site.

Inclusion Criteria

- Any patient (male or female) over 18 years old, with or without HIV, with a histologically confirmed diagnosis of high grade Anal high-grade squamous intraepithelial lesion or Intraepithelial Neoplasia or Squamous Cell Carcinoma.

Exclusion Criteria

- Patient under the age of 18 years
- Prospective patient (diagnosed after 15/01/2024) that refuses informed consent
- Prospective patient (diagnosed after 15/01/2024) that does not have the capacity to consent to be take part
- Patients with histology other than Squamous Cell Carcinoma

Primary Objectives

- Investigate demographic risk factors of patients with anal SCC
- Determine risk factors for anal squamous intraepithelial lesions (SIL) progression to SCC
- Investigate best treatment for patients with multifocal low-grade disease
- Compare end outcomes of different anal SCC and SIL management guidelines from different centres

We expect there to be many more potential objectives and the data can be utilised to answer any relevant scientific research question related to anal SCC, pending REC approval for individual projects.

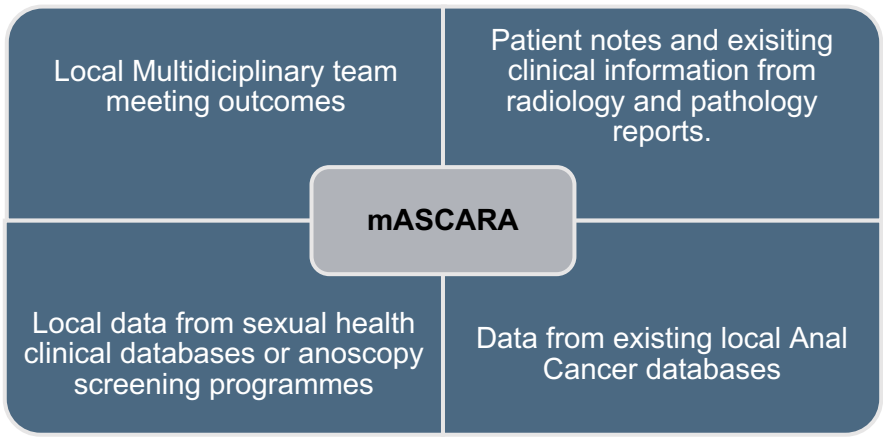

Figure 2: Potential Data Sources

Demographics	HIV	Sexual Health	Surveillance	Pathology	Oncological Treatment	Recurr-ence	Survival
Age	Date of Diagnosis	Anal warts	Previous anal SIL diagnosis	Staging	Chemotherapy	Date	5 year survival
Sex	AIDS	Receptive anal intercourse	Anal SIL grade at first diagnosis	Tumour differentiation	Radiotherapy	Local vs. distant	Disease free
Co-morbidities	Viral load	Hepatitis C/ B	Method of anal SIL diagnosis	Surgical treatment	Staging after treatment	Salvage surgery	Date of death
ASA grade/ performance status	CD4 count	Illicit drug use	Participation in screening		Reason for unsuitability for CRT.	R0/R1 resection outcomes	Cause of death
Smoking	Antiretrovirals used	Other HPV dysplasia or malignancy	Number of anoscopies		Last date of follow up	Reason for not having further treatment	
Immunosuppression	Compliance	HPV cytology	Date of HSIL diagnosis				

Figure 3: Outcomes to be included in Database

Access to mASCARA

After successful registration and local research and Information governance approval. A password protected account will be provided to registered members of the direct care team. If you have a large dataset already available electronically, contact the study coordinator (chelwest.mascararegistry@nhs.net) as it may be possible to upload the dataset directly.

Role in Study	Name and Qualifications	Experience
Chief Investigator and Data Controller	Miss Sarah Mills BSc (Hons) BMCCh MD (Res) FRCS	Consultant Colorectal Surgeon Chelsea and Westminster Hospital NHS Foundation Trust and Honorary Clinical Senior Lecturer Imperial College London
Co-Investigator	Professor Paris Tekkis BMedSci, BM BS, MD, FRCS	Professor of Colorectal Surgery Imperial College London, Royal Marsden NHS Foundation Trust and Chelsea and Westminster Hospital NHS Foundation Trust
Co -Investigator	Mr Christos Kontovounisios MD PhD FRCS	Consultant Colorectal Surgeon Chelsea, Honorary Clinical Senior Lecturer Imperial College London
Study Co-ordinator	Ms Micol Lupi BSc (Hons), MBBS, MRCS	Colorectal Registrar Chelsea and Westminster Hospital NHS Foundation Trust, Research Fellow at Imperial College London
Data Custodian	Professor Paul Elliot	Head of Department of Epidemiology and Biostatistics Imperial College London.

Figure 4: Study Management Group

Study Co-ordination

The day-to-day management of mASCARA will be co-ordinated through the study co-ordinators. If there are any further questions regarding mASCARA please email (chelwest.mascararegistry@nhs.net).

Withdrawal Criteria

Patients with their data included after informed consent can request to be removed at any point in the study and, if possible, their data will be discarded.

If a patient asks to be withdrawn the direct care team will be informed and asked to identify the randomly allocated patient identification number from their pseudonymisation list. The patient data can then be deleted by an administrator.

However, as analysis will be randomised, it will be impossible to delete data from previous downloaded versions of the data and previous analyses. The patient information leaflet clearly explains that depending on the time of the request we will be able to delete the patients record from the database but may not be able to prevent their data being used in analysis.

Adverse Events

Due to the nature of this study, adverse events are unlikely. However, should any occur they will be referred immediately to the Chief Investigator and Imperial College London's Standard Operating Procedures would apply.

Funding

mASCARA is being supported by the Red Trouser Day Charity.