

# Oral topical cyclo-oxygenase 2 inhibitors (COX2-1) mouthwash for the treatment of oral dysplasia

<b>Submission date</b> 23/04/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 29/03/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-study-using-aspirin-for-pre-cancerous-white-patches-mouth-ASPOD>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

2007-003292-40

### ClinicalTrials.gov (NCT)

NCT01238185

### Protocol serial number

6070

# Study information

## Scientific Title

Oral topical cyclo-oxygenase 2 inhibitors (COX2-1) mouthwash for the treatment of oral dysplasia: a pilot non-randomised interventional proof of concept study

## Acronym

ASPOD

## Study objectives

Pilot study assessing the potential role of aspirin in treating oral dysplasia.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

West Midlands REC approved on the 24th September 2009 (ref: 08/H1208/49)

## Study design

Non-randomised interventional treatment trial

## Primary study design

Interventional

## Study type(s)

Treatment

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

Topic: National Cancer Research Network, Ear; Subtopic: Head and Neck Cancer, Ear (all Subtopics); Disease: Head and Neck, Ear, nose & throat

## Interventions

Group 1: Standard dispersible tablets of aspirin 75 mg (BNF) and be instructed to disperse one tablet thoroughly in one glass of 250 ml of water and use as mouthwash for 60 seconds twice a day.

Group 2: Two standard dispersible tablets of aspirin 75 mg (BNF) and will be instructed to dissolve the two tablets thoroughly in one glass of 250 ml of water and use as mouthwash for 60 seconds twice a day.

Group 3: Standard dispersible tablets of aspirin 300 mg (BNF) and be instructed to disperse one tablet thoroughly in one glass of 250 ml of water and use as mouthwash for 60 seconds twice a day.

Group 4: Standard dispersible tablets of aspirin 300 mg (BNF) and be instructed to dissolve the one tablet thoroughly in one glass of 250 ml of water and use as mouthwash for 60 seconds three times a day.

Patients will use the mouthwash for 6 weeks until they return for their second biopsy. Follow up is then whatever is required by the clinical team.

Study entry: registration only

## **Intervention Type**

Drug

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Aspirin

## **Primary outcome(s)**

Level of COX expression, prostaglandin level and change in histological grade measured pre- and post-treatment. Measurement of the primary outcome measures will only occur once all patients have been recruited to the study. Pre and post treatment biopsy samples (6 weeks apart) are snap frozen and stored at -80°C.

## **Key secondary outcome(s)**

All biochemical measures for the secondary outcomes will be measured at the same time. The histological grade of the tissue will be made within 7 - 10 days of each biopsy being taken as is normal clinical practice for these lesions. The tolerability and side effects will be ascertained on the patients return for their second biopsy (6 weeks after commencing the Aspirin).

## **Completion date**

03/10/2011

# **Eligibility**

## **Key inclusion criteria**

1. Patients with clinically evident leukoplakia
2. Can attend follow up
3. Requiring biopsy and surgery
4. 18 years old or over, either sex
5. Able to give informed consent
6. Not known to be pregnant

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

## **Age group**

Adult

## **Lower age limit**

18 years

## **Sex**

All

**Total final enrolment**

13

**Key exclusion criteria**

1. Histologically confirmed cancer
2. Prior oral cancer
3. Patients on aspirin, non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroid treatment
4. Current treatment of oral dysplasia with topical/systemic treatment
5. Active peptic ulcer disease
6. History of aspirin induced asthma, stomach ulcers or aspirin sensitivity
7. History of associated angioedema, urticaria or suspected aspirin allergy in the past

**Date of first enrolment**

01/02/2010

**Date of final enrolment**

03/10/2011

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

Clifford Bridge Road

Coventry

United Kingdom

CV2 2DX

**Sponsor information****Organisation**

Coventry University Hospital (UK)

**ROR**

<https://ror.org/025821s54>

**Funder(s)**

Funder type

Charity

### Funder Name

Cancer Research UK (CRUK) (UK) (ref: C19677/A8556)

### 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

Not provided at time of registration

### IPD sharing plan summary

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	25/06/2012		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Plain English results</a>		20/11/2013	29/03/2022	No	Yes