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

Submission date 23/04/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/04/2010	**Overall study status** Completed	
Last Edited 29/03/2022	**Condition category** Cancer	

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

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT01238185

Clinical Trials Information System (CTIS)
2007-003292-40

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 practive 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?
Results article	results	25/06/2012		Yes	No
HRA research summary			28/06/2023	No	No
Plain English results		20/11/2013	29/03/2022	No	Yes