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Influence of MLH1 gene on anti-neoplastic effects of Resistant Starch

Submission date 22/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/11/2005	**Overall study status** Completed	
Last Edited 10/09/2012	**Condition category** Cancer	

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/preventing-bowel-and-rectal-cancer-with-aspirin-and-starch

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
To test the hypothesis that individuals with certain genetic make up (MLH1 gene* deficient) are more susceptible to the anti-cancer effects of Resistant Starch**.
* MLH1 gene is one of the DNA mismatch repair genes. These genes help to correct the errors during DNA replication.

** Resistant Starch is a part of our normal dietary intake. It is a type of starch which is resistant to the action of digestive enzymes in the small gut and hence reaches the large bowel undigested. These undigested starches are fermented by bacteria in the large bowel to form short chain fatty acids like butyrate, acetate and propionate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Colorectal cancer

Interventions
Colonic mucosal biopsies from tumour and normal mucosa will be obtained from all consented volunteers at the time of endoscopy. Then they will be randomised into two groups, one group will get resistant starch (30 g per day) and the second group will get ordinary starch (30 g per

day) for a period of 2-4 weeks depending on the duration between diagnosis and the definitive surgery (colectomy). Post treatment samples from tumour and normal mucosa will be obtained from resected specimens.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Resistant starch

Primary outcome measure
Difference in gene expression, cell proliferation and apoptosis in the pre treatment and post treatment samples and in patients with and without a functioning MLH1 gene.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2005

Completion date
30/06/2006

Eligibility

Key inclusion criteria
All individuals who are found to have a colorectal lesion suspicious of malignancy which would require an elective operation at the time of colonoscopy/flexible sigmoidoscopy.
About 10%-12% of all sporadic colorectal cancers have defective MLH1 gene (Lothe RA, Cancer Res 1993). By recruiting all sporadic colorectal cancer patients we will have recruited individuals both with and without loss of function of the MLH1 gene and hence, we will be able test our hypothesis that the MLH1 gene influences response to Resistant Starch.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria

1. Patients who have had a subtotal colectomy with an ileorectal anastamosis (insufficient length of functioning large bowel for the resistant starch to have effect)
2. Patients with ileostomy or a diversion colostomy (resistant starch will not reach the colonic lumen)
3. Individuals who are not capable of giving their informed consent
4. Individuals who cannot continue taking the oral supplements for any reason
5. Pregnant women (effect of resistant starch in pregnant women and foetuses has not yet not evaluated)

Date of first enrolment
01/07/2005

Date of final enrolment
30/06/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Human Nutrition Research Centre
Newcastle Upon Tyne
United Kingdom
NE2 8NH

Sponsor information

Organisation
Northumbria Healthcare NHS Trust (UK)

Sponsor details
North Tyneside General Hospital
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Sponsor type
Hospital/treatment centre

Website
http://www.northumbria-healthcare.nhs.uk

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Research council

Funder Name
The Biotechnology and Biological Sciences Research Council (BBSRC) (UK) - (Grant ref no.-13 /D20173)

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?
Results article	results	01/03/2009		Yes	No