

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

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

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

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Patients who have had a subtotal colectomy with an ileorectal anastomosis (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

United Kingdom

England

Study participating centre

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

Sponsor information

Organisation

Northumbria Healthcare NHS Trust (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

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