What are the advantages and disadvantages for me if I take part in the study?

Although the study drug is being tested as a treatment for a condition that you have, you will not receive any medical benefit from it. This is a double blinded study which means that neither you nor the study staff will know if you have received the investigational product or a placebo (dummy drug).

However, you can expect to:

- be compensated for your time and commitment
- have your health closely monitored and receive a comprehensive medical examination
- have the personal satisfaction of contributing towards medical research

Your wellbeing is our main concern

Research studies are carefully designed by highly trained and experienced clinicians to answer specific research questions.
A protocol (design of a study) must be approved by an independent ethics committee to ensure that the wellbeing of volunteers is safeguarded.
As with all medications there are possible side-effects, the details of this will be thoroughly discussed by your consultant or a Quintiles physician before you choose whether to participate in the trial.

What if you change your mind?

Your participation is voluntary and you may withdraw from the study at any point should you so wish, without giving any reason.

How can I find out more?

Visit: www.quintilesclinicaltrials.co.uk /register-for-top-3/
and complete the questions.

Or contact Quintiles directly on 0207 910 7700

*Quintiles Drug Research Unit at Guy's Hospital is part of Quintiles Limited and is independent of The Guy's and St Thomas' NHS Foundation Trust

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Ulcerative Colitis *study*

TOP1288

A CLINICAL STUDY FOR A POTENTIAL NEW TREATMENT FOR ULCERATIVE COLITIS

What's *involved* in *this* study?

Are you interested in taking part in a clinical trial?

We are looking for male and post-menopausal female patients suffering from ulcerative colitis, having been diagnosed more than 6 months ago and currently experiencing mild to moderate symptoms (with blood in your motion), to take part in a clinical study for a potential new treatment for the condition.

As the world's largest clinical research organisation, Quintiles carries out clinical studies to improve medical treatments. We hope this trial will help future patients suffering from Ulcerative Colitis.

You should be:

- otherwise well with no requirement for steroids treatment for the last 3 months and
- only taking a stable course of oral Mesalazine (Aminosalicylic acid) for at least 4 weeks (common preparations include AsacolR, OctasaR, MezavantR, PentasaR and SalofalkR).

What is a clinical study?

All new drugs, whether they are for simple ailments or ground-breaking cancer treatments, must go through a strictly monitored clinical trial process before they can be prescribed by a doctor or sold in a pharmacy. Clinical research is conducted on behalf of the pharmaceutical industry, the NHS or a health charity.

This particular study for the potential treatment of Ulcerative Colitis is being carried out on behalf of TOPIVERT Pharma Limited, with MHRA (Medicines and Healthcare products Regulatory Authority) approval in accordance with UK laws and independent ethics approval.

Development of a new drug may take over ten years and testing in humans only takes place after detailed laboratory investigations and it is deemed safe to do so. All drug development has to go through a set number of stages. This is a Phase I study and there is no therapeutic benefit to patients, whilst they're on the study.

Why is this study taking place?

There is a need for new and improved drugs as current treatments do not control the disease in all patients, some of whom need surgery to remove the colon.

The drug being tested in this study is Top1288. It has the potential to treat patients and belongs to a new class of drugs called narrow spectrum protein kinase inhibitors. It has an anti-inflammatory action and works from inside the bowel cavity on the inner lining of the bowel wall which is the site of the inflammation in ulcerative colitis.

TOP1288 has been tested already in healthy volunteers and deemed safe and well-tolerated. This part of the study will be to check that this holds true in ulcerative colitis patients and determine whether the disease influences the way the body handles the medication in terms of its absorption and elimination.

What will happen to me if I do agree to take part in this clinical study?

If you would like to take part in this trial please consult your doctor or research nurse who will advise if you are eligible. If you are, you will be given more information on the trial and direct contact details of a member of our Quintiles team. Once you have been in touch; we have answered any of your questions and you decide that you would like to go on the trial, you can arrange an initial screening appointment that will be held at Quintiles' unit located near London Bridge.

The screening visit lasts approximately two hours and will include:

- A full medical and physical examination carried out by a doctor
- ECG, weight, height, blood and urine tests

During this appointment you will have a chance to speak to a study doctor to discuss any information about the study and to confirm whether or not you would like to take part. After your appointment, we will contact you (generally within 7–10 days) about the results of your tests and let you know if you are suitable to participate.

What will happen when I am on the study?

You will stay in the unit for 5 nights and 6 days and will be asked to return for a final follow up visit approximately 7 days after discharge. During the inpatient stay prior to receiving the study drug you will have a bowel examination (sigmoidoscopy) and a number of small tissue samples will be taken. This is conducted routinely in patients with bowel disorders and you will be familiar with the procedure.

Will I receive any payment for taking part in the study?

Yes, there will be a payment for participation if you complete the study:

- with once daily dosing you will be compensated £3,460
- with twice daily dosing you will be compensated £4,260

Payment is approved by an independent medical ethics committee and is considered a fair amount for your time and commitment.