Survey for ASTUTE clinical trial

Survey for ASTUTE clinical trial

Please would you take the time to answer this brief survey about whether you would support a new UK clinical trial in uveitis

The NHS recognises a need to obtain research about new treatments for rare autoimmune conditions. In response to this, a group of uveitis doctors in England are proposing a new study to test how well adalimumab works to treat autoimmune uveitis in patients who either have active eye disease or who need high doses of other drugs and consequently are at risk of common and serious side effects.

Right now, patients with sight-threatening uveitis in England are only rarely offered treatment with adalimumab because the NHS consider that there is insufficient evidence that this drug is effective and cost-effective. The research that has been done shows that adalimumab is effective compared with no treatment rather than existing treatments. In reality, most patients can be safely treated with other drugs and then use adalimumab if necessary. This new trial reflects this reality by testing the effectiveness of adalimumab combined with safe, low doses of the drugs that are usually prescribed compared to treatment with the usual drugs alone.

We have designed the study with features that we believe should make it attractive to patients with sight-threatening uveitis and to the NHS. The process of judging competing applications for funding will decide how well the study addresses the NHS' priorities – and we would like to ask you whether you think that the study will also appeal to patients who would be eligible to participate in the trial. Eligible patients would be patients with active disease or those that are taking amounts of existing treatments that would put them at risk of side effects.

The initial trial period

A standard trial would usually compare the drug we are testing against another drug. Our trial is different because we would like to make sure as many people have the opportunity to be treated as possible for a four month period at least. This means everyone gets the test drug (adalimumab) .This widening of eligibility usually has the effect of showing when the test drug is ineffective and in whom it is ineffective. If a patient's uveitis does not get better, then they will stop adalimumab end of 4 months.

Not everyone responds to a particular treatment though, so widening eligibility increases the risk of recruiting people who are unlikely to benefit. In the initial phase of the trial, if a patient's uveitis does not get better, then they will stop adalimumab at

the end of 4 months.

The doctors proposing this research are confident that patients whose disease is still active at the end of the trial period are very unlikely to benefit from adalimumab.

Pease state country where you live

Email address (optional, but useful if in the UK and you would like to be invited into the study)

Type of uveitis with cause eg idiopathic, sarcodosis, PIC, birdshot, scleritis, other etc

Default Question Block

1. Do you agree with widening eligibility for the initial trial period ie. everybody has a chance to be treated with adalimumab for 4 months?

- ○ Strongly agree
- ○ Agree
- ○ No opinion
- ○ Disagree
- ○ Strongly disagree

Any comment

2. Do you agree that it is acceptable to stop adalimumab at the end 4 months period for patients whose disease is not controlled?

- ○ Strongly agree
- ○ Agree
- ○ No opinion
- ○ Disagree
- ○ Strongly disagree

Any comment

Main study treatment

After 4 months' initial treatment period, patients who have a positive response to adalimumab then join the main study where they receive adalimumab or a dummy treatment on top of a safe, low dose of existing treatment and are followed up until the end of the trial. This is the only way for us to test how well the drug works. This is because we can't be sure that it is the drug we are testing is responsible for controlling the disease in all of these patients. We appreciate that it may seem unfair to switch half of the patients from active to dummy treatment. Therefore, we propose to switch patients to the other treatment if their eye inflammation gets worse. This would mean that patients would have the chance of access to adalimumab in the main study also. It is really important that nobody knows while the trial is happening, what medications patients are on. This ensures we don't treat patients differently and influence the results in any way. Patients, nurses and doctors will not know who is on what drug, usually until the end of the trial. Of course, if there is a serious side effect then this rule does not apply if we need to know what medication the patient was on.

3. Do you agree that switching treatment in the event of disease relapse is a good way to reassure patients in the main study about the chance of being assigned to the dummy treatment?

- ○ Strongly Agree
- ○ Agree
- ○ No opinion
- ○ Disagree
- ○ Strongly disagree

Any comment

4. Do you agree that switching treatment provides a good way to keep patients in the main study for as long as possible?

- ○ Strongly Agree
- ○ Agree
- ○ No opinion
- ○ Disagree
- ○ Strongly disagree

Any comment

5. Do you agree that offering patients the opportunity to remain in the study until the overall results are known is a good way to manage patients' access to the active drug?

- ○ Strongly Agree
- ○ Agree
- ○ No opinion
- ○ Disagree
- ○ Strongly disagree

Any comment

6. Would you be interested in participating in this trial?

- ○ Strongly Agree
- ○ Agree
- ○ No opinion
- ○ Disagree
- ○ Strongly disagree

Any comment

7. Would it be acceptable to you if a generic version of adalimumab were used? i.e a 'biosimilar' to the commercially available, branded adalimumab drug?

- ○ Strongly Agree
- ○ Agree
- ○ No opinion
- ○ Disagree
- ○ Strongly disagree

Any comment

8. Would you be interested in helping with the trial from a patient perspective?

- ○ Strongly Agree
- ○ Agree
- ○ No opinion
- ○ Disagree
- ○ Strongly disagree

Any comment