NHS

National Research Ethics Service

Salford & Trafford Research Ethics Committee
Room 181
Gateway House
Piccadilly South
Manchester
M60 7LP

Tel: 0161 237 2336
Fax: 0161 237 2383

04 August 2009

Sister Yoke Mei McLoughlin
Rheumatology Nurse Specialist
Rheumatology Dpt
Trafford General Hospital
Davyhume, Manchester
M41 5SL

Dear Sister McLoughlin

Study title:	**Full title: Is a single dose intramuscular (IM) triamcinolone acetonide injection more effective in treating symptomatic flare in established rheumatoid arthritis than equivalent dose of oral prednisolone?**
REC reference:	**07/H1004/193**
Protocol number:	**1.1**
EudraCT number:	**2007-006729-28**

Thank you for sending the declaration of end of study form and final summary report, notifying the Research Ethics Committee that the above study concluded on 30 June 2009. I will arrange for the Committee to be notified.

07/H1004/193: **Please quote this number on all correspondence**

Yours sincerely

pp **Carol Ebenezer**
Committee Co-ordinator

E-mail: carol.ebenezer@northwest.nhs.uk

Copy to: Dr Sarah Ryan – Keele University School of Medicine
Trafford NHS Trust

End of Study Report – Dated 19 July 2009

REC Reference number: 07/1004/193
EudraCT number2007-006729-28
Short Title of Study: Treatment Comparison for Symptomatic Flare in RA

30 patients were enrolled and randomised. No participants withdrew from the study and there were no serious adverse events reported.

The results indicated that there was a reduction in values over time for both groups, but that this reduction was significantly greater in the Kenalog IM group. At week 2 there was a mean difference in disease activity score (DAS28) of 1.9 units between the two groups, whilst at week 4 there was a mean difference of 0.9 units between the two groups which was of borderline significance ($p=0.05$). There was no significant difference between groups at either week 6 or week 8. Both treatments demonstrated a reduction in disease activity in the short-term; however IM triamcinolone acetonide demonstrated a magnitude of effect at weeks 2 and 4 which was greater than that of oral prednisolone.

The difference detected between the two groups in terms of magnitude and duration of effects on clinical and laboratory parameters of disease activity measured suggests that IM Kenalog is faster acting and has a greater magnitude of effect than oral prednisolone for up to 4 weeks from commencement of treatment.

In conclusion it is felt that, in addition to acting faster and with a greater magnitude of effect, a single dose of IM triamcinolone acetonide has a distinct advantage in terms of convenience of administration and assured patient concordance with treatment. Furthermore it is considered that these findings support the alternative hypothesis that IM Kenalog is more effective than oral prednisolone. It is recommended however that further studies be conducted in order to gain much stronger evidence in support of these findings.

End of Study Report – Dated 19 July 2009

REC Reference number: 07/1004/193
EudraCT number2007-006729-28
Short Title of Study: Treatment Comparison for Symptomatic Flare in RA

30 patients were enrolled and randomised. No participants withdrew from the study and there were no serious adverse events reported.

The results indicated that there was a reduction in values over time for both groups, but that this reduction was significantly greater in the Kenalog IM group. At week 2 there was a mean difference in disease activity score (DAS28) of 1.9 units between the two groups, whilst at week 4 there was a mean difference of 0.9 units between the two groups which was of borderline significance ($p=0.05$). There was no significant difference between groups at either week 6 or week 8. Both treatments demonstrated a reduction in disease activity in the short-term; however IM triamcinolone acetonide demonstrated a magnitude of effect at weeks 2 and 4 which was greater than that of oral prednisolone.

The difference detected between the two groups in terms of magnitude and duration of effects on clinical and laboratory parameters of disease activity measured suggests that IM Kenalog is faster acting and has a greater magnitude of effect than oral prednisolone for up to 4 weeks from commencement of treatment.

In conclusion it is felt that, in addition to acting faster and with a greater magnitude of effect, a single dose of IM triamcinolone acetonide has a distinct advantage in terms of convenience of administration and assured patient concordance with treatment. Furthermore it is considered that these findings support the alternative hypothesis that IM Kenalog is more effective than oral prednisolone. It is recommended however that further studies be conducted in order to gain much stronger evidence in support of these findings.