

Nottingham BMRP projects

Hookworm vs Crohns Disease
Stem Cell Transplantation for CD



Hookworm Background

- CD rare where parasites common
- Parasites induce Th1 to Th2/Treg switch
- *Trichuris suis* has raised the principle of parasite Rx
- Hookworm expertise in Nottingham
- Interest in microbe derived molecules
- Can deliver predictable stable dose

Human hookworms



Crohn's Patients Queensland

- 9 Crohn's patients
- 3 RAs
- Original 5 CD reinfected weeks 27-30
- All 5 in remission at week 45

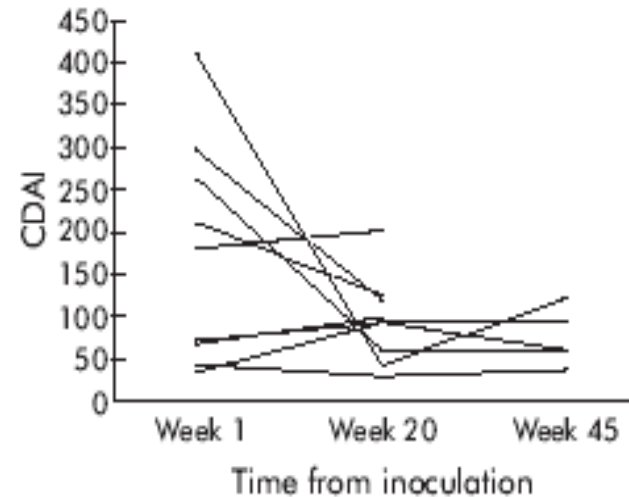
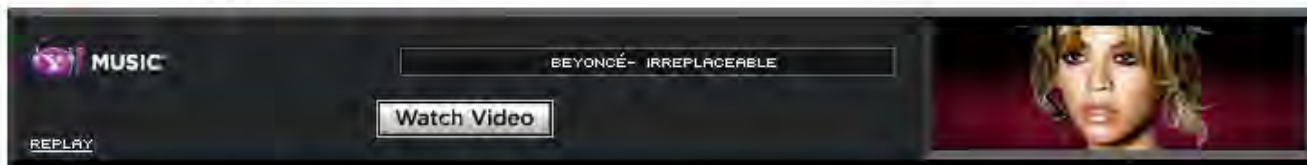


Figure 1 Initial Crohn's disease activity index (CDAI) score for each CD patient versus score at week 20 and at week 45 for the first five inoculated cases (mean 165 (95% confidence interval 145) v 64 (25), $p=0.132$; mean 165 v 75 (29), $p=0.246$).



Home
Messages

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Members Only

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Home

Activity within 7 days: **13** New Messages - New Questions

Description

A forum and support group for those considering or undergoing helminthic therapy. See Wikipedia at http://en.wikipedia.org/wiki/Helminthic_therapy for a description and definition.

A place to share experiences, compare notes and meet people in the same boat as you.

Diseases that have been demonstrated to respond are Asthma, Allergies, Eczema, Crohn's, Ulcerative Colits or Multiple Sclerosis, and in one anecdotal account, Autism.

Helminthic therapy is in its early stages. So there is plenty to learn.

Editorial Policy: This group is moderated. I will only approve posts that meet the following conditions:

1. Posts must be on topic, concerning helminthic therapy.
2. Commercial posts are allowed, so long as they conform to 1. above and are clearly labeled as such with "Commercial Post" included in the title. Person posting must clearly state their interest in the company or product being promoted within that post. If you have a product or company in this process, please provide your details and URL and

Info Settings

Group Information

Members: 37
 Category: Procedures and Therapies
 Founded: Jul 13, 2007
 Language: English

Autoimmune Therapies

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[Is it Right for Me?](#)
[About the Company](#)
[Science](#)
[Patient Stories](#)
[Links](#)
[Our Staff](#)
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Helminthic Therapy



Necator Americanus L3 infectious larvae, x400, the organism used in helminthic therapy.

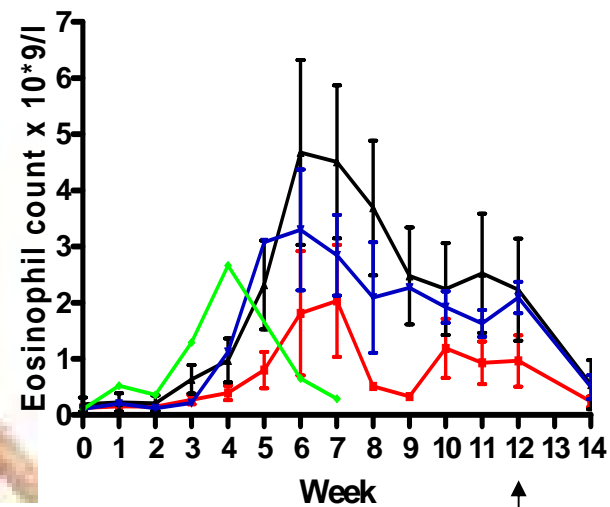
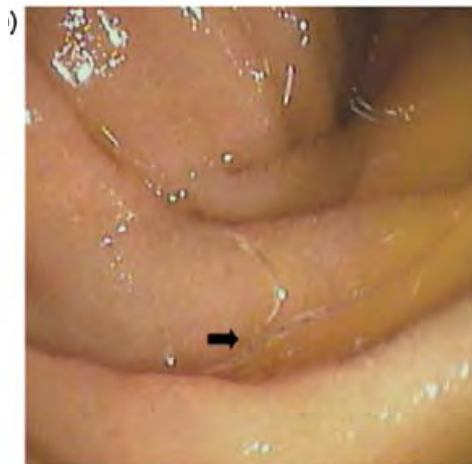
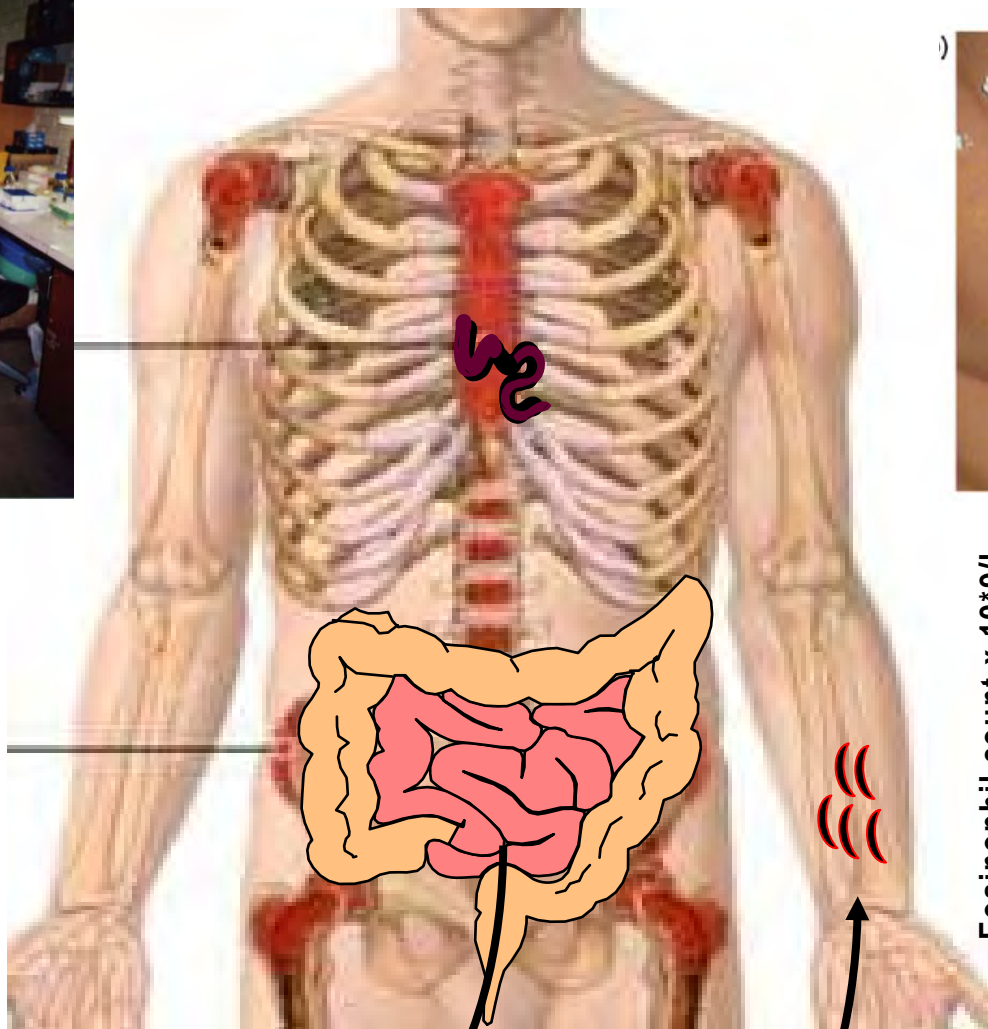
Autoimmune Therapies provides **helminthic therapy** to those with asthma, Crohn's disease, ulcerative colitis, psoriasis, multiple sclerosis and allergies, using safe, physician supervised inoculation with hookworm (*Necator Americanus*, see above). We obtain, isolate and purify our hookworm using the same method developed and used in medical studies at Universities throughout the world, to ensure the safety of our patients.

My interest is personal: I put my severe asthma and seasonal allergies into remission using the same

Nottingham HATrIC study



Hookworms **A**s **T**reatment In **C**rohn's Disease



Eggs in feces



TRIAL
10 hookworm larvae
Vs placebo (histamine)

↑
CDAI
at
week
12

HATrIC

Screened: 82

Randomised: 43

Completed: 38

Target: 56

Issues

- Unusual group of patients
- Patients want naturotherapy
- (Investigators want patentable NCE!!)
- Unusual treatments attract unusual patients
 - Not all have CD
 - CD may be atypical
 - Not all have active CD (CDAI low)
 - Not all have active CD (CDAI high)
- Potential for placebo response and CDAI variation unrelated to disease activity
- Some non-CD patients are very persistent
- HIT-UC trial is planned

Why we need to try to cure CD

1993 Ileal CD (age 9) - elemental diet and steroids

4.03 **Ileocaecal resection** 55cm, ischaemic perforation, stoma

9.03 Reversal

12.03 Relapse (steroids and aza)

1.04 **Pancreatitis**

2.04 **Perianal abscess** drainage, seton and IFX 3 infusions – 2-3 weeks response

MTX : nausea, vomiting

8.04 **Laparotomy** for obstruction. Trans-sphincteric fistula drained; further setons

11.04 WCE – scattered aphthoid ulcers throughout bowel

12.04 IFX – **perianal/labial abscess** 10 days later, with arthralgia; polymeric diet

3.05 15cm **ileal segment resected**; TPN

5.05 **PEG feeding**

8.05 recurrent **perianal abscess**

9.05 Balloon enteroscopy: ulcers in duodenum and jejunum, strictures on MRE

9.05 IFX arthralgia despite steroids

1.06 **IFX anaphylactoid reaction**

2.06 Adalimumab (160mg/40mg weekly, 6 weeks) initial response good

4.06 Perianal abscess/fistula

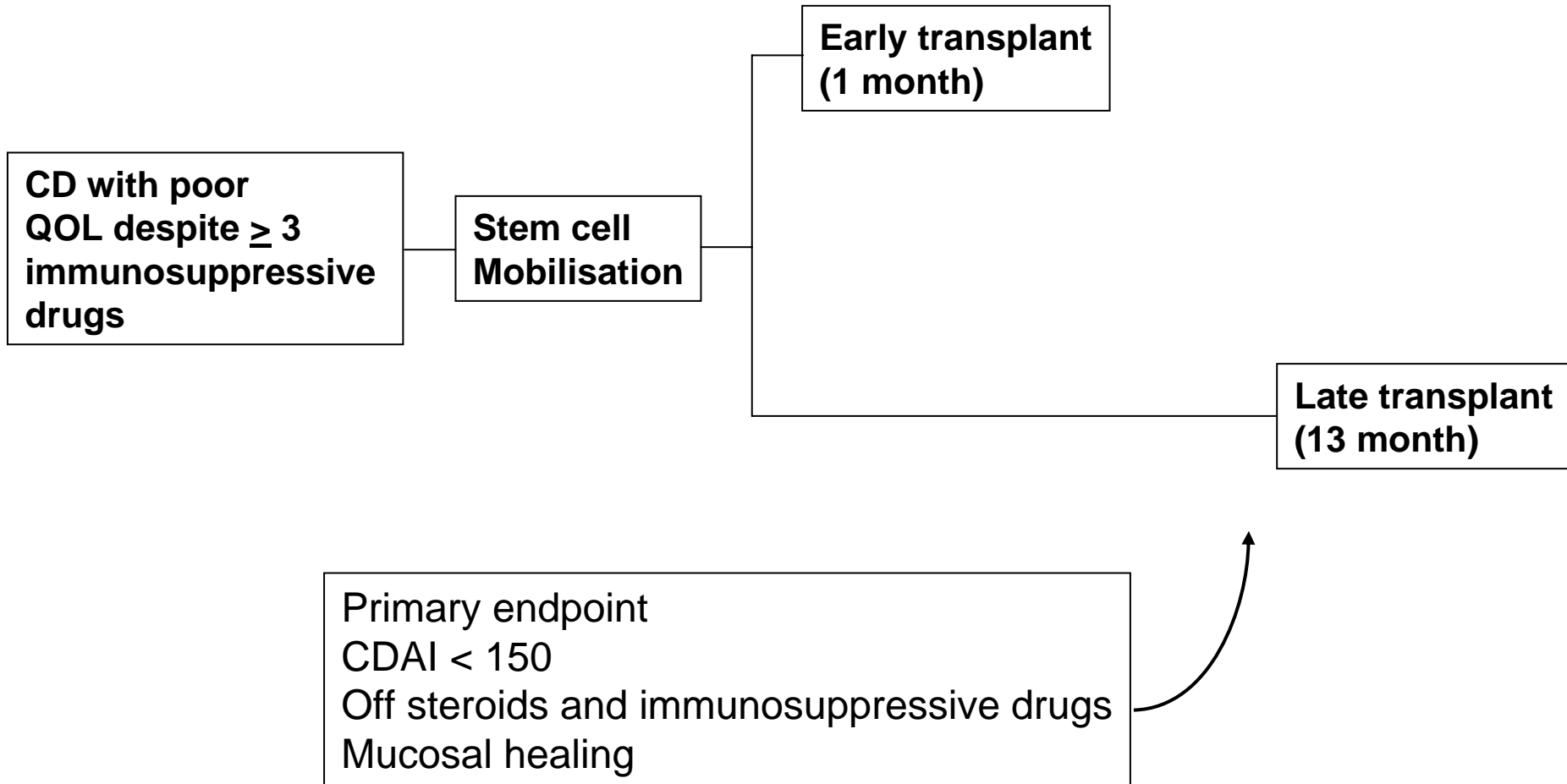
ASTICS trial

Autologous Stem Cell Transplantation In Crohn's Disease

ECCO / EBMT Trial

www.astic.eu

ASTIC Trial



ASTIC Progress

Entered trial: 3

Randomised: 2

Approved and waiting: 4

In the wings: 5-6

Enquiries: 2/month (UK)

Issues

- Registration difficulties
 - UK, France, Spain, Italy, Czech Rep, Canada, (Switzerland)
- Competing trials
- Major undertaking
 - MHRA
 - European clinical trials directive
 - Multi-Centre
 - Staffing
 - Solution: Run by CRO (2 CRAs)
- Adverse effects of Rx (NOD-2)



Acknowledgements

- Hookworm
- Alan Buchanan (Supplies)
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- Lisa Chalkley
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- Julie Sutton
- (Site visits and monitoring)
- Executive: Silvio Danese, Mathieu Allez, Dominique Farge
- Evaluation committee
- DSMC
- Investigators

