TOPPIC

Trial of Prevention of Post-Operative Crohn's Disease

Add New Candidate

Gender:	
Date of Birth:	
Proceed to visit – 1:	
Reason for making this patient a non-recruit:	
If ineligible, ineligible reason:	
If declined, declined reason:	
Any other details:	
Decision date:	

Visit No. 1

INCLUSION CRITERIA		EXCLUSION CRITERIA	
2. Established diagnosis of Crohn's:		**2. Known intolerance to GMP**	
3. Resection:		**3. Pancreatitis assoc. with Azathioprine**	
Ileocolonic resection date		**6. Stricturoplasty procedure alone:**	
7. Screening consent form signed		**7. Stoma:**	
		11. History illicit drug or alcohol abuse in past year:	
		12. History of cancer:	
		Is subject breastfeeding?:	

SCREENING SAMPLES			
Screening consent date:			
Samples take date:			
Samples taken for screening:		**Screening results:**	
TPMT:	**Yes/No**	**TPMT Result:**	
Stool:	**Yes/No**	**Positive Stool Result:**	

Disease

SAFETY BLOOD SAMPLES	
Safety bloods taken:	**Yes/No**
Date taken:	
SAFETY BLOOD RESULTS	
***Any* LFT>x2 upper limit of normal:**	
Haemoglobin <10:	
White blood cell count <3.5:	
Neutrophils <1.5:	
Platelets <100x10^6/1:	

Have you:

- **Dispensed CDAI?**
- **Dispensed stool specimen pot?**

VISIT 2 – Consent and Physical Exam

Has subject signed study consent form?:	
Consent form date:	
Has subject agreed to provide a genetic sample?:	

Physical Examination

Date of exam:		**Smoking status**	
Units of alcohol per week:		**If current, how many a day?:**	
Weight:		**If former when stopped:**	
Height:			
B.P.			
Heart rate:			

General Appearance:	
Skin:	
Head/Neck/ENT:	
Cardiovascular:	
CNS:	
Respiratory:	
GI:	

Visit 2 – Eligibility Check

INCLUSION CRITERIA		EXCLUSION CRITERIA	
		1. Pregnant:	
1. At least 16 years of age		**1. Breastfeeding**	
2. Established diagnosis of Crohn's disease confirmed at recent resection:		**2. Known hypersensitivity to GMP**	
3. Ileocolonic resection within three months:		**3. Pancreatitis associated with Azathioprine**	
4. No more than 100cm of bowel resected:		**4. Receiving experimental Crohns treatment in 4 weeks prior to study:**	
5. Able to start oral nutrition within first 2 post-op weeks:		**5. Known to require further surgery:**	
6. Normal or heterozegenous TPMT:		**6. Stricturoplasty procedure alone:**	
7. Has provided written informed consent:		**7. Presence of stoma:**	
8. Off antibiotics 2 weeks prior to randomisation:		**8. Significant haematological, renal or hepatic dysfunction:**	
		9. Systemic infection:	
		10: Diagnosis of colitis:	
		11: History of illicit drug or alcohol abuse:	
		12: History of cancer:	
		13: Presence of condition that places subject at unacceptable risk:	
		14: Homozygous deficient for TPMT:	
		15: Evidence of untreated post-op infection:	

Visit 2 – Bloods Taken

Haematology:	
Biochemistry:	
ESR:	
Plasma Viscosity:	
6-MP Metabolite level:	
Faecal Calpotectin:	
Genetic studies:	
Serological studies:	

Pregnancy Record

Subjects partner's current pregnancy status:	
Pregnancy notified at visit number:	
EDD:	
Pregnancy outcome:	
Outcome date:	
If delivered, select method:	
If aborted, select details:	

CDAI Diary

	1. Total no of liquid or very soft stools daily	2. Abdominal pain rating daily	3. General wellbeing daily
Day 1:			
Day 2:			
Day 3:			
Day 4:			
Day 5:			
Day 6:			
Day 7:			

4. Presence of complications: Are there any complications:	
Arthritis:	
Iritis or uveitis:	
Erythema nodosum or pyoderma gangrenosum:	
Anal fissure, fistula or abscess:	
Fever >37.8 in the last week:	

5. Use of medications: Were any of the medications listed below used:		
Loperamide:	**Codeine:**	**Other antidiarrhoeals:**

6. Abdominal mass:

7. Haematocrit level:	
	This result is entered by the Central Trial Office

8. Body weight (kg)	
	This data is entered at the Physical Exam for the visit

CDAI Total Score: ***Need to supply stool number for each day***

Adverse Events

Description:	
Is this surgical intervention for Crohn's?:	
Start date (DD MMM YYYY):	
Reported to (initials):	
Severity:	
Causality:	
Action taken:	
Outcome:	
If led to SAE, Describe:	
Resolved date (DD MMM YYYY):	
Ongoing (at trial end):	

Physical Exam

Physical Examination			
Date of exam:		**Smoking status**	
Weight:		**If current, how many a day?:**	
B.P.		**If former when stopped:**	
Heart rate:		**Alcohol units per week:**	
General Appearance:			
Skin:			
Head/Neck/ENT:			
Cardiovascular:			
CNS:			
Musculoskeletal:			
Respiratory:			
GI:			

Bloods Taken

Haematology:	
Biochemistry:	
ESR:	
Plasma Viscosity:	
6-MP Metabolite level:	
Faecal Calpotectin:	
Genetic studies:	
Serological studies:	

Medical History

Condition/Operation:			
Start Date:	**DD:**	**MMM:**	**YYYY:**
Stop Date:	**DD:**	**MMM:**	**YYYY:**
Current related concomitant meds?:			
Ongoing? (Trial End)			

Medications:

Medication:			
Is this a prohibited medication?:			
Is this rescue therapy for Crohn's?:			
Does this medication coupled with the IMP introduce a risk to the patient?:			
Is it an antacid?:			
Is it an Anti Diarrhoeal Agent?:			
Is it a Spasmodic Agent?:			
Treatment of AE?:			
Indication:			
Route:			
Dose:			
Frequency:			
Start Date:	**DD:**	**MMM:**	**YYYY:**
Stop Date:	**DD:**	**MMM:**	**YYYY:**
Ongoing? (Trial End)			

Crohn's History

Active Visit:			
Visit No. 2: outcome:			
Actual Date:		**Scheduled Date:**	

Crohn's Disease History:		
Date of first symptoms:	**Month:**	**Year:**
Date of Diagnosis:	**Month:**	**Year:**
Age at Diagnosis:		
Disease Location:		
Disease Behaviour:		

Surgical History:					
Number of Operations:					
Operation date (most recent first)		**Operation type**	**Was any other + Stricturoplasty disease observed?:**	**Length of Bowel resected:**	
M:	**Y:**				
M:	**Y:**				
M:	**Y:**				

Total time on no medication since diagnosis:		**Total time on SASA or topical Rx:**		**Total time on steroids/immunosuppressives:**	
Yrs:	**Mnths:**	**Yrs:**	**Mnths:**	**Yrs:**	**Mnths:**

Severity of symptoms prior to diagnosis:	
Pain:	
Diarrhoea:	
Anorexia:	
Fever:	

Bleeding:	
Is there a history of IBD?:	
If yes, specify:	

Crohn's Disease Therapy:			
		Dates:	**Reason for Stopping:**
Previous Infliximab:			
Azathioprine:			
6MP:			
5-ASA:			
(5-ASA Brand):			
Methotrexate:			
Topical Treatments:			
Other Carticosteroids:		**Description:**	

Extra-Intestinal Manifestations:	
Arthralgia/Arthritis:	
Iritis/Euveitis:	
EN/Pyoderma/Athous Stomatitis:	
Anal Fissure/Fistula/Abscess:	
Other Fistula:	

Drug Accountability

PREVIOUS PRESCRIPTION DETAILS:	
Dispensed Date:	
No of tablets dispensed:	
No of tablets expected to be taken:	
RETURNED TABLETS DETAILS:	
No of tablets returned:	
Discrepancy:	
Comments:	