ASEPTIC Trial
Primary Antibiotic Prophylaxis using Co-trimoxazole to prevent SpontanEous Bacterial PeritoniTIs in Cirrhosis

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No conflicts of interest

Thanks to an Amazing Team for ATTIRE

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Recruiting Hospitals
Basildon, Basingstoke, Bristol Royal Free Royal London, Newcastle, Hull North Tees, South Tees, Brighton Liverpool, Royal Singleton, Wales Queens, Birmingham, Southampton, Leeds, Glasgow, Gloucs, Whittington, Oxford, Wigan, Nottingham, Plymouth, Derby, Plymouth, Brighton, Durham, Coventry

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Going to do it Again!!! – a mere 550 patients

Primary Antibiotic prophylaxis using co-trimoxazole to prevent SpontanEous bacterial PeritoniTIs in Cirrhosis

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Infection

- Big problem in cirrhosis
- Defective immune response
- Risk SBP of 20-25% within 2 years + Low AF prot
- SBP mortality 20–40%
- 90% of cases present with no previous episode
- Prevention may be better than cause
- Not Quinolones: AMR, SAEs

Double blind RCT

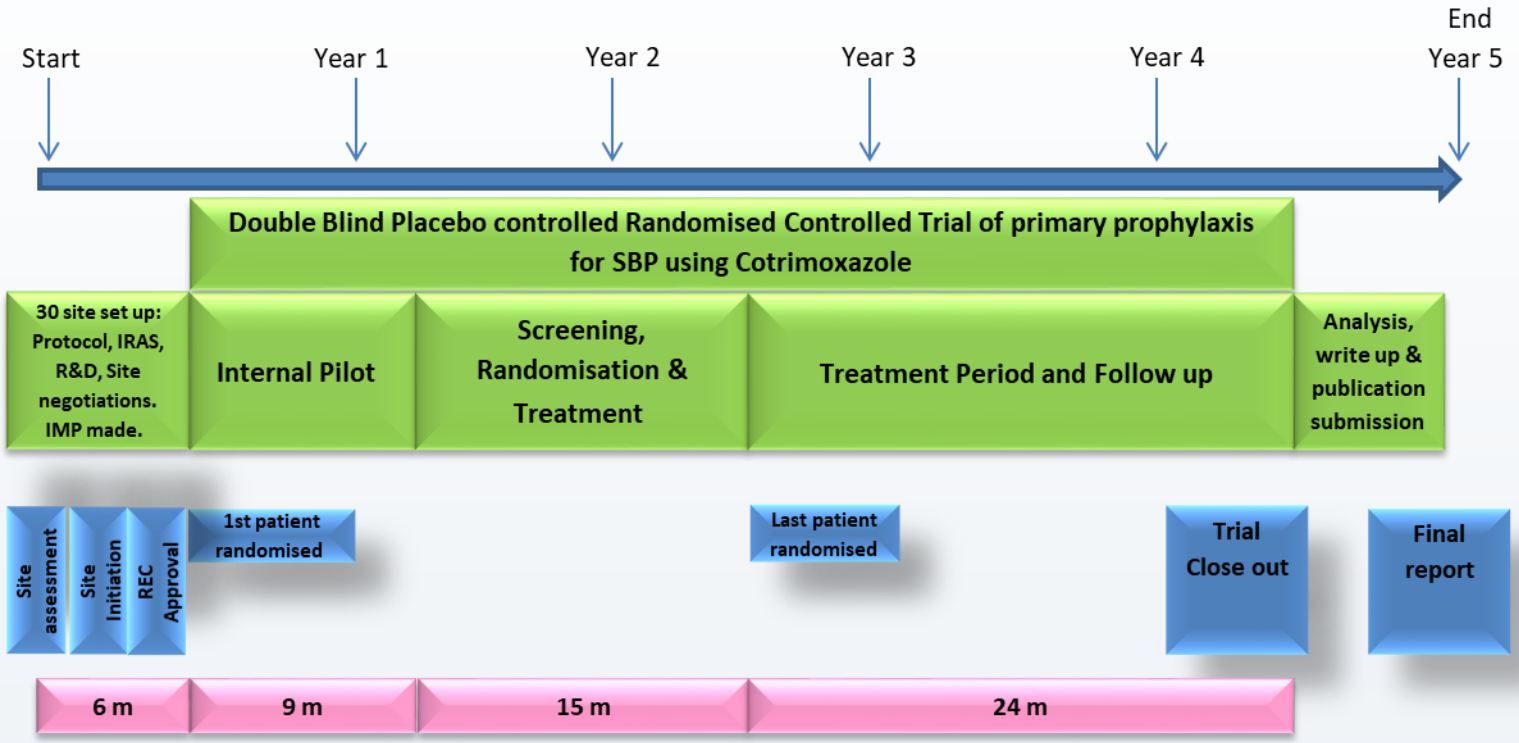
- Submit to REC this week
- Over encapsulate 2 tablets
- 960mg bd
- Pragmatic
  - Advise about hyperkalaemia – stop/start
  - Cessation at admission
  - Stratify for rifaximin
  - Data collection
- PIS & PIV

Sample Size

Control incidence (at two years)	Time to event (Hazard ratio)		
	0.4	***0.45***	0.5
25%	400 (58)	492 (74)	616 (95)
22.5%	446 (58)	***548 (74)***	686 (95)
20%	502 (58)	618 (74)	774 (95)

per treatment arm), with 90% power and two-sided 5% significance level. It is estimated that as many as 30% of participants may undergo transjugular intrahepatic portosystemic shunt insertion (TIPS), liver transplant, ascites resolves or they die over a 2 year period. These patients will all be included within the analysis and will be censored at the point at which they are no longer considered at risk i.e. transplanted/TIPS/improve. The calculation allows for 20% loss-to-follow-up (withdrawal/loss-to follow-up/resolution of ascites/ transplant) at 24 months

ASEPTIC Project Plan



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Further information

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