



Mitochondrial Anti-oxidant therapy to
Resolve Inflammation in Ulcerative Colitis



The **MARVEL** Study

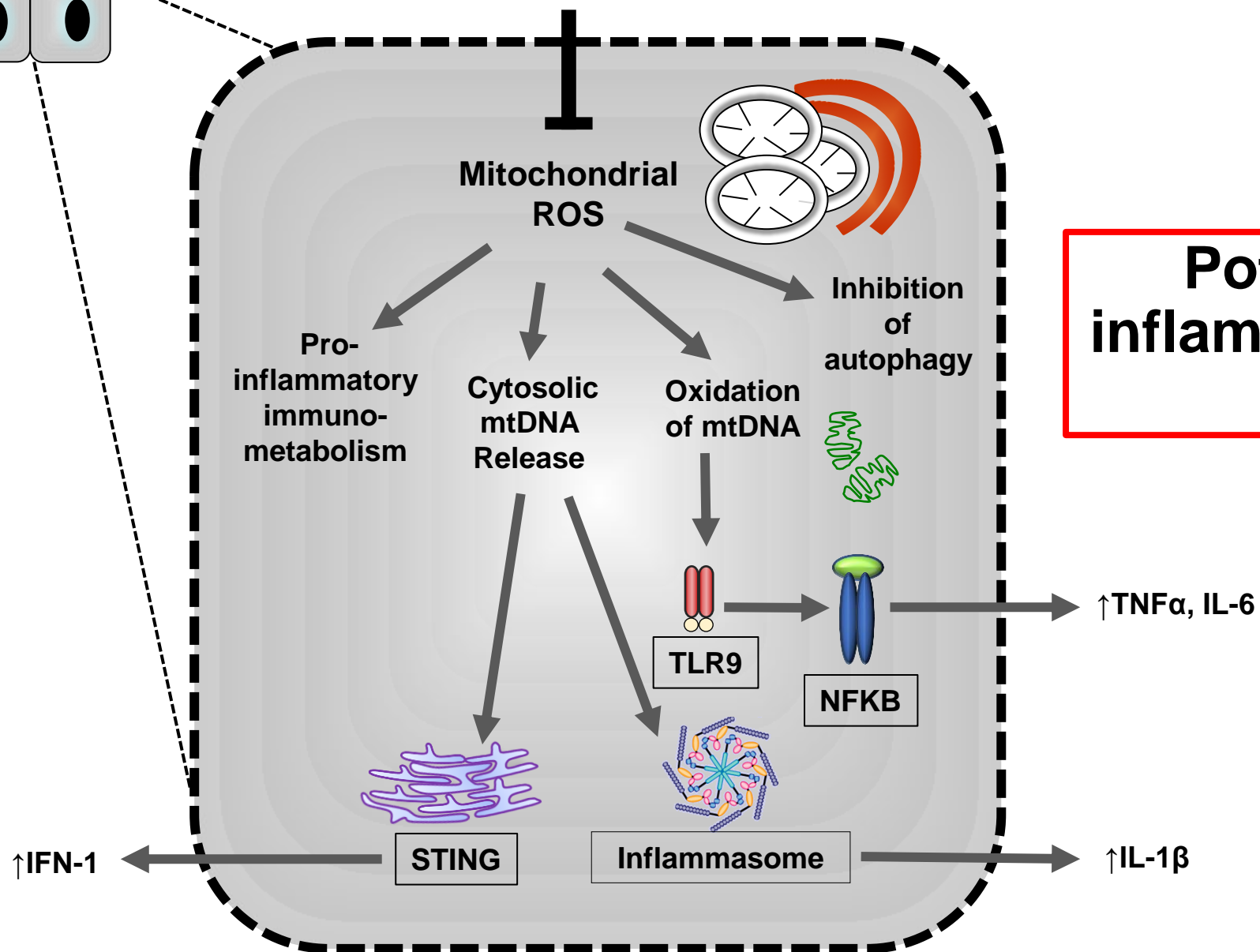
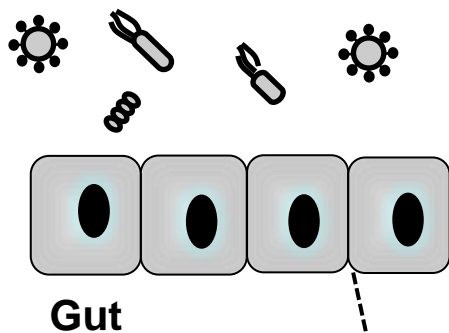
BSG IBD Investigators Meeting
29/01/2024

Dr Rebecca Hall
Clinical Research Fellow/Associate PI

Mitochondrial Dysfunction in UC

- MARVEL: Mitochondrial anti-oxidant therapy to resolve inflammation in UC
- Previous work investigating mitochondrial dysfunction and ROS production in IBD
- Mitoquinol (MitoQ): Commercially available mitochondrial antioxidant, improvement in experimental colitis mouse models

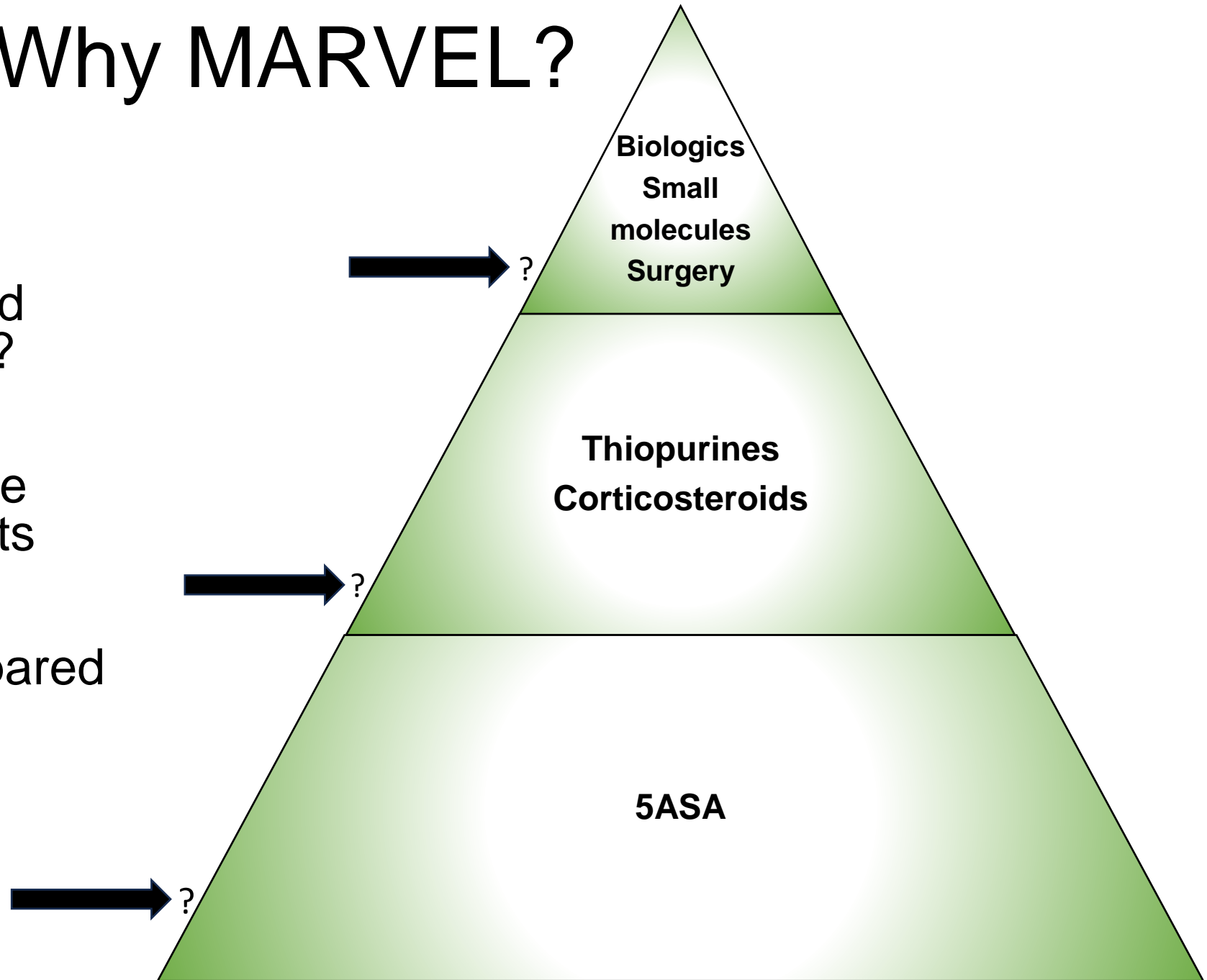
Anti-inflammatory effects of MitoQ on Mitochondrial ROS



Potential anti-inflammatory effects of MitoQ

Why MARVEL?

- Can we identify an interim treatment prior to advanced therapies or as an adjunct?
- Potentially more acceptable treatment option for patients
- More budget friendly compared to other treatments





Mitochondrial Antioxidant Therapy to Resolve Inflammation in Ulcerative Colitis

[For Participants](#)

[For Investigators](#)

A project by the Gut Research Unit [↗](#)
Centre for Inflammation Research
University of Edinburgh



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- CI: Dr Gwo-tzer Ho
- Phase 2b, placebo-controlled, double-blinded RCT (206 patients)
- Adjunct to Prednisolone treatment in flare of UC
- Advanced therapy naïve or off treatment for ≥ 1 year
- Extent beyond proctitis
- NIHR Portfolio Study
- Jon Moulton Foundation

www.marvelstudy.uk

UC Flare



Screening
(Max 2 weeks)

Mitochondrial antioxidant vs placebo (24 weeks duration)



Oral Prednisolone 40mg (tapering by 5mg/week)

Week 0

Week 8

Week 12

Week 24

Primary Endpoint
Clinical response
Full Mayo Score

Secondary Endpoint
Clinical remission
Treatment escalation

Patient Reported Outcome: Partial Mayo Score and CUCQ32 q4

MARVEL Evolution

2009-2017

Damaged gut mitochondria in IBD are pro-inflammatory
Could this be a treatment target?

2018

MARVEL study funded

2020

Covid-19

September 2021

MHRA Approval

May 2022

Opens in Edinburgh

2022 – 2023

More centres join
Teething problems navigated

August 2023

Paused for IMP stability testing (passed until end 2025)

January 2024

2 CCUK Research Champions join the team

MARVEL Progress

Participants randomised: 36

Centres opened: 8

Edinburgh WGH/RIE

Glasgow QUEH/GRI

Dundee Ninewells Hospital

Chelsea and Westminster Hospital

Pinderfields Hospital

Darlington Memorial Hospital

St George's Hospital

North Durham University Hospital

Prospective centres

Hull

Cardiff

Cambridge

Oxford



Challenges

- **Timescales**

- Time sensitive – 7-day screening window
- Requirement for negative stool culture result prior to randomization

- **Logistics**

- Endoscopy
- Sending stool cultures
- 2 separate visits required at baseline

- **Recruitment**

- Unpredictable
- All or nothing!



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Next Steps

- **Research Champions/PPI Group**
 - Research Champions Tricia Kelly and Emma Pryde recently joined PPI team
 - Develop plans to promote MARVEL and boost recruitment
- **Boost recruitment 2024**
 - Slowed due to hiatus Summer 2023
- **Liaising with prospective new sites**
 - Get in touch if interested in joining!
 - Open to Associate PI scheme
- **Amendment to allow earlier treatment start**
 - Coming soon, pending R&D approval
- **All ages IBD research**
 - Paediatric arm: Mini-MARVEL



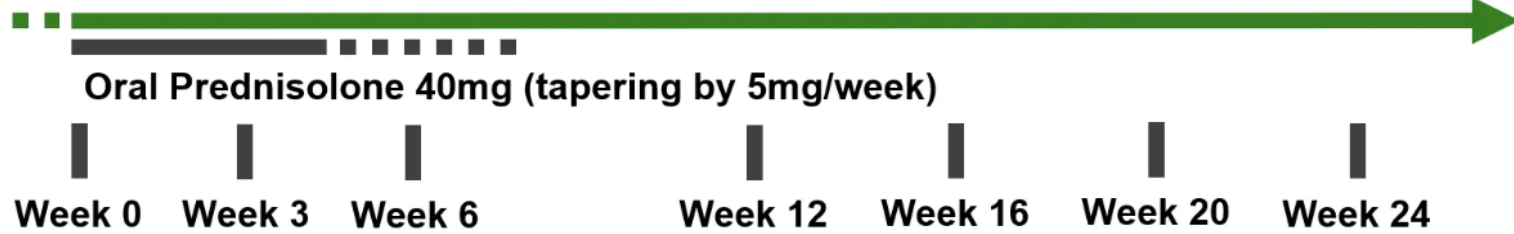
UC Flare or new UC

mini-**Ma**rvel

Screening

(Max 2 weeks)

Mitochondrial antioxidant vs placebo (24 weeks duration)



Primary Endpoint
Feasibility

Secondary Endpoint
PUCAI Score
Clinical Response
Steroid Burden

Patient-Reported Outcome
TUMMY-UC Score

Phase 2b feasibility RCT placebo-controlled double-blinded

120 Paediatric-UC participants across UK

Coming soon....

Get in touch



www.marvelstudy.uk



@Edin_IBDScience

@MarvelTrial



MARVEL.Trial@ed.ac.uk



[The journey of science to clinical trial](#) (blog post)



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Acknowledgements



THE UNIVERSITY of EDINBURGH
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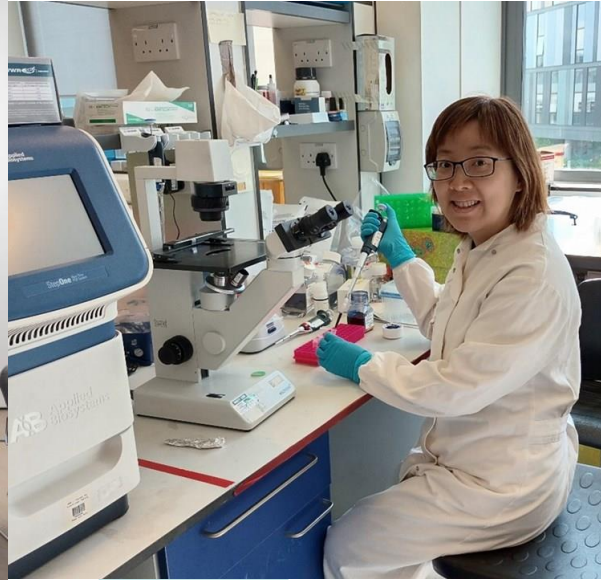
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Ma rvel

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