

The antibiotic crisis: Is there a role for traditional herbal remedies?

The ATAFUTI project: testing the antimicrobial potential of bearberries

Professor Michael Moore on behalf of the ATAFUTI trial team

Alternative Treatments for Adult Female Urinary Tract Infection:
a double blind randomised controlled study.

What is the problem?

- 80% of antibiotics originate in primary care
- The majority are prescribed for self limiting conditions
 - Sore throats 60%
 - Acute bronchitis 60%
 - Urinary tract infection 93%

Potential strategies

- Improved communication skills
- Clinical scores
- Near patient tests
- Delayed prescribing
- Better symptom relief

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- Clinical scores
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- **Better symptom relief**

Urinary Tract Infections

- UTIs are common
- The symptoms associated with UTIs are distressing.
(These usually settle without complications within 3 - 4 days but antibiotics do shorten the duration of symptoms)
- A delayed prescription strategy may help
(It reduces antibiotic prescribing rates for respiratory infections)
- In UTI delayed strategy unlikely to be widely adopted without better symptom relief

Trial Objectives

Two candidates for **symptom relief** have been identified.

- **Ibuprofen** Shown in one small study to provide good symptom relief in UTI with only 33% of participants requiring antibiotics.
- **Uva Ursi**, Known as bearberry, a herbal product which has been used as a traditional treatment for urine infections.

• **Primary objective:** To compare whether ibuprofen or Uva Ursi provide *relief from urinary symptoms* in adult women with a suspected UTI.

• **Secondary objective** Do ibuprofen or Uva Ursi result in *reduced antibiotic uptake*

What is bear berry?



Arctostaphylos uva-
ursi

- Dried Leaf



Trial Design

- Factorial Design
 - Uva ursi + ibuprofen
 - Placebo + ibuprofen
 - Uva ursi no ibuprofen
 - Placebo no ibuprofen
- Five days of trial medication and a delayed prescription for antibiotics.
- Delay antibiotics if possible.
- Symptom diary for 2 weeks.
- Notes review will be carried out 3 months following recruitment to document return visits to surgery with a UTI.

Progress to date

Timeline	Action
December 2010	Application to SPCR
March 2011	Outline application to SPCR- withdrawn due to non availability of uk product Uvacin
February 2012	Herbal supplier identified funding application to SPCR
April 2012	Funding approved!
March 2013	No progress with herbal formulation Switch supplier new contracts
June 2013	Manufacturer unable to source ibuprofen- switch to alternative supplier
May 2014	Import of herb raw ingredients and production of herbal product commence stability testing
September 2014	Stability testing results prepare investigator brochure and submit application to MHRA

School for Primary Care Research

The National Institute for Health Research School for Primary Care Research (NIHR SPCR) is a partnership between the Universities of Birmingham, Bristol, Keele, Manchester, Nottingham, Oxford, Southampton and University College London.



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Health Research**

Progress to date

Feb 2015	MHRA approval
Feb 2015	MHRA withdraw Manufacture (IMP) license from supplier of ibuprofen
Feb-March	Re-write protocol, materials, database- resubmit ethics and MHRA
April 2015	Trial unable to complete in timeframe of contracts Re-application to SPCR for new funding
June 2015	MHRA and ethics approval for modified protocol
July 2015	SPCR re-funding approved
August 2015	Study opens

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Progress to Date

- 4th Augusts 1st site opens
- 12th August first patient in trial
- 30th November 63 participants

- Target recruitment 328
- Need to recruit 45 participants a month to achieve target by end of May 2016

Future developments

- *Pelargonium sidoides*
- *Andrographis paniculata*



Any Questions?



The ATAFUTI study is funded by the National Institute for Health Research School for Primary Care Research (NIHR SPCR). The views expressed are those of the author and not necessarily those of the NHS, the NIHR or the Department of Health.

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