UCON Trial:
Ulipristal versus Coil for the
Management of Heavy Menstrual Bleeding

Baseline Questionnaire (incl. UFS-QOL)

Please complete this questionnaire now to help us find out how your heavy menstrual bleeding affects your quality of life.

All your answers will remain strictly confidential. The nurse will check through the questionnaire to make sure you have answered every question, but these questions will not be used to determine which treatment you will have.

There are no right or wrong answers. We are just interested in your own views about your symptoms and how you feel about life in general.

Try not to dwell too long on any question, and choose the answer that comes closest to how you have been feeling generally. It is important to get complete information so please answer all the questions even if some may seem repetitive or less relevant.

Thank you for your participation in this study.

Completed by participant: Date Completed: D D - M M M - Y Y Y Y

Completed by hospital trial staff: UCON Trial No. | | | | | Patient Initials | | |

For UCON Trial Office Only: Date Form Entered: D D - M M M - Y Y Y Y

SECTION A: Impact of your periods on your day to day life

These questions refer to your menstrual cycle or period. If you are no longer having regular periods, please complete the questions below as best you can. There will be an opportunity to discuss your periods in a later section. In each of the following areas of health, tick the statement that best applies to you in the right hand box. Please only tick one statement in each area.

1. Practical difficulties

1. I have no practical difficulties, bleed no more than I expect and take no extra precautions..... ☐
2. I have to carry extra sanitary protection with me but take no other precautions..... ☐
3. I have to carry extra sanitary protection and clothes because of the risk of flooding..... ☐
4. I have severe problems with flooding, soil the bedding and need to be close to the toilet..... ☐

2. Social life

1. My social life is unaffected during my cycle. I can enjoy life as much as usual..... ☐
2. My social life is slightly affected during my cycle. I may have to cancel or modify my plans..... ☐
3. My social life is limited during my cycle. I rarely make any plans..... ☐
4. My social life is devastated during my cycle. I am unable to make any plans..... ☐

3. Psychological health

1. During my cycle I have no worries I can cope normally..... ☐
2. During my cycle I experience some anxiety and worry..... ☐
3. During my cycle I often feel down and worry about how I will cope..... ☐
4. During my cycle I feel depressed and cannot cope..... ☐

4. Physical health and wellbeing

1. During my cycle I feel well and relaxed. I am not concerned about my health..... ☐
2. During my cycle I feel well most of the time. I am a little concerned about my health..... ☐
3. During my cycle I often feel tired and do not feel especially well. I am concerned about my health.. ☐
4. During my cycle I feel very tired and do not feel well at all. I am seriously concerned about my health ☐

5. Work/ daily routine

1. There are no interruptions to my work/daily routine during my cycle..... ☐
2. There are occasional disruptions to my work/daily routine during my cycle..... ☐
3. There are frequent disruptions to my work/daily routine during my cycle..... ☐
4. There are severe disruptions to my work/daily routine during my cycle..... ☐

6. Family life/ relationships

1. My family life/ relationships are unaffected during my cycle..... ☐
2. My family life/ relationships suffer some strain during my cycle..... ☐
3. My family life/ relationships suffers quite a lot during my cycle..... ☐
4. My family life/ relationships are severely disrupted as a result of my cycle..... ☐

Reference: Shaw RW, Brickley MR, Evans L, Edwards MJ. Perceptions of women on the impact of menorrhagia on their health using multi-attribute utility assessment. BJOG. 1998;105(11):1155-9.

SECTION B: About your periods and pelvic pain

1. How regular is your cycle?

Regular, I know when to expect my period..... ☐

Fairly regular, my period starts within a few days of when I expect..... ☐

Irregular, I cannot predict when my period will start..... ☐

I have bleeding on and off all the time..... ☐

2. What is the average duration of your period?

1 - 3 days..... ☐

4 – 6 days..... ☐

More than 6 days..... ☐

3. Do you experience pelvic pain during your periods?..... Yes ☐ No ☐ Pelvic pain but no regular periods ☐

If 'yes' or have pelvic pain but no regular periods please circle the number on the line to indicate how much pain during your periods you had in the last 4 weeks.

0 1 2 3 4 5 6 7 8 9 10

No pain at all — Worst imaginable pain

4. Do you experience pelvic pain during intercourse?..... Yes ☐ No ☐ Not applicable (not sexually active) ☐

If 'yes' please circle the number on the line to indicate how much pain during intercourse you had in the last 4 weeks.

0 1 2 3 4 5 6 7 8 9 10

No pain at all — Worst imaginable pain

5. Do you experience pelvic pain at any other times (other than during period or during intercourse) Yes ☐ No ☐

If 'yes' please circle the number on the line to indicate how much pain at times other than period or during intercourse, you had in the last 4 weeks.

0 1 2 3 4 5 6 7 8 9 10

No pain at all — Worst imaginable pain

SECTION C: Impact of fibroids on your day to day life

Listed below are symptoms experienced by women who may have uterine fibroids. Please consider each symptom as it relates to **your uterine fibroids or menstrual cycle**. Each question asks how much distress you have experienced from each symptom during the **previous 3 months**.

There are no right or wrong answers. Please be sure to answer every question by ticking the most appropriate box. **If a question does not apply to you, please mark "not at all"** as a response.

During the **last three months** how distressed were you by:

	Not at all	A little bit	Somewhat	A great deal	A very great deal
1. Heavy bleeding during your menstrual period	☐	☐	☐	☐	☐
2. Passing blood clots during your menstrual period	☐	☐	☐	☐	☐
3. Fluctuation in the duration of your menstrual period compared to your previous cycles	☐	☐	☐	☐	☐
4. Fluctuation in the length of your monthly cycle compared to your previous cycles	☐	☐	☐	☐	☐
5. Feeling tightness or pressure in your pelvic area	☐	☐	☐	☐	☐
6. Frequent urination during the daytime hours	☐	☐	☐	☐	☐
7. Frequent night-time urination	☐	☐	☐	☐	☐
8. Feeling fatigued	☐	☐	☐	☐	☐

Please also answer the questions below **and** on the **next page** which ask about your feelings and experiences regarding the impact of uterine fibroid symptoms on your life. Please consider each question as it relates to your experiences with uterine fibroids during the previous 3 months.

There are no right or wrong answers. Please be sure to answer every question by ticking the most appropriate box. If a question does not apply to you, please mark "none of the time" as a response.

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
9. Made you feel anxious about the unpredictable onset or duration of your periods?	☐	☐	☐	☐	☐
10. Made you anxious about travelling?	☐	☐	☐	☐	☐
11. Interfered with your physical activities?	☐	☐	☐	☐	☐
12. Caused you to feel tired or worn out?	☐	☐	☐	☐	☐
13. Made you decrease the amount of time you spent exercise or other physical activity?	☐	☐	☐	☐	☐
14. Made you feel as if you are not in control of your life?	☐	☐	☐	☐	☐
15. Made you concerned about soiling underclothes?	☐	☐	☐	☐	☐
16. Made you feel less productive?	☐	☐	☐	☐	☐
17. Caused you to feel drowsy or sleepy during the day?	☐	☐	☐	☐	☐
18. Made you feel self-conscious of weight gain?	☐	☐	☐	☐	☐

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
19. Made you feel that it was difficult to carry out your usual activities?	☐	☐	☐	☐	☐
20. Interfered with your social activities?	☐	☐	☐	☐	☐
21. Made you feel conscious about the size and appearance of your stomach?	☐	☐	☐	☐	☐
22. Made you concerned about staining bed linen?	☐	☐	☐	☐	☐
23. Made you feel sad, discouraged or hopeless?	☐	☐	☐	☐	☐
24. Made you feel downhearted and low?	☐	☐	☐	☐	☐
25. Made you feel exhausted?	☐	☐	☐	☐	☐
26. Caused you to be concerned or worried about your health?	☐	☐	☐	☐	☐
27. Caused you to plan activities more carefully?	☐	☐	☐	☐	☐
28. Made you feel inconvenienced about always carrying extra pads, tampons, and clothing to avoid accidents?	☐	☐	☐	☐	☐
29. Caused you embarrassment?	☐	☐	☐	☐	☐
30. Made you feel uncertain about your future?	☐	☐	☐	☐	☐
31. Made you feel irritable?	☐	☐	☐	☐	☐
32. Made you concerned about soiling outer clothing?	☐	☐	☐	☐	☐
33. Affected the size of clothing you wear during your period?	☐	☐	☐	☐	☐
34. Made you feel that you are not in control of your health?	☐	☐	☐	☐	☐
35. Made you feel weak as if energy was drained from your body?	☐	☐	☐	☐	☐
36. Diminished your sexual desire?	☐	☐	☐	☐	☐
37. Caused you to avoid sexual relations?	☐	☐	☐	☐	☐

Reference: Spies JB, Coyne K, Guaou Guaou N, Boyle D, Skyrnarz-Murphy K, Gonzalves SM. The UFSQOL, a new disease-specific symptom and health-related quality of life questionnaire for leiomyomata. Obstet Gynecol. 2002;99(2):290-300. Reproduced with permission from SIR Foundation.

SECTION D: Sexual Activity

Although the following questions are sensitive and personal, they are important in determining how different treatments affect this part of your life. Please be assured that your responses to these questions will remain confidential.

	Yes	No
1. Are you currently married or having an intimate relationship with someone?.....	☐	☐
2. Have you changed your sexual partner in the last 6 months?.....	☐	☐
3. Do you engage in sexual activity with anyone at the moment?.....	☐	☐

If you answered yes to question 3, go to 'Sexually Active Questions'

Not Sexually Active Questions

I answered no to question 3. I am not sexually active at the moment because: (Please tick as many of these items as apply)

a)	I do not have a partner at the moment.....	☐
b)	I am too tired.....	☐
c)	My partner is too tired.....	☐
d)	I am not interested in sex.....	☐
e)	My partner is not interested in sex.....	☐
f)	I have a physical problem which makes sexual relations difficult or uncomfortable.....	☐
g)	My partner has a physical problem which makes sexual relations difficult or uncomfortable.....	☐
h)	Other reasons (please describe.....	☐

Sexually Active Questions

Please complete this section if you are sexually active (i.e. you answered yes to Section C - question 3).

Please read each of the following questions carefully and tick the box that best indicates your sexual feelings and experiences during the past month:

	Very Much	Somewhat	A Little	Not at all
1. Was 'having sex' an important part of your life this month?.....	☐	☐	☐	☐
2. Did you enjoy sexual activity this month?.....	☐	☐	☐	☐
3. In general, were you too tired to have sex?.....	☐	☐	☐	☐
4. Did you desire to have sex with your partner(s) this month?.....	☐	☐	☐	☐
5. During sexual relations, how frequently did you notice dryness of your vagina this month?	☐	☐	☐	☐
6. Did you feel pain or discomfort during penetration this month?.....	☐	☐	☐	☐
7. In general, did you feel satisfied after sexual activity this month?.....	☐	☐	☐	☐

	5 times or more	3–4 times	1-2 times	Not at all
8. How often did you engage in sexual activity this month?.....	☐	☐	☐	☐

	Much more	Somewhat more	About the Same	Less than Usual
9. How did this frequency of sexual activity compare with what is usual for you?.....	☐	☐	☐	☐

	Very Much	Somewhat	A little	Not at all
10. Were you satisfied with the frequency of sexual activity this month?.....	☐	☐	☐	☐

Any comments_____

_____

Reference: Thirlaway K, Fallowfield L, Cuzick J. The Sexual Activity Questionnaire: a measure of women's sexual functioning. Qual Life Res. 1996;5(1):81

SECTION E: Questions about any treatments you have had or are now taking

1. What medical treatment(s) do you take for your heavy menstrual bleeding OR as contraception? Indicate as many as applicable. Please include treatments that you were taking recently, but were asked to stop, in order to participate in the UCON Trial.

	Yes	No		Yes	No
Ulipristal tablets……	☐	☐	LNG-IUS (Coil)……	☐	☐
Mefenamic acid (Ponstan)……	☐	☐	Depo-provera injection……	☐	☐
Contraceptive pill……	☐	☐	If you are taking the pill, please tell us how you take the pill:	Yes	No
Please state Contraceptive Brand_____			Cyclical (*with a 7 day break*) 21-day pack	☐	☐
			OR	Yes	No
			Continuous (without a break) 28-day pack	☐	☐

	Yes	No		Yes	No
No medical treatment……	☐	☐	Tranexamic acid (Cyclokapron)……	☐	☐
Other Treatment……	☐	☐			

Please state Other Treatment name_____

2. Employment status, are you currently:

Full time work……	☐	Student……	☐
Occassionally/ Casual Work……	☐	Unemployed……	☐
Homemaker……	☐	Retired ……	☐
Part time work……	☐	Other……	☐

If other, please state_____

SECTION F: General Quality of Life

Under each heading, please tick the **ONE** box that best describes your health **TODAY.**

MOBILITY

I have no problems in walking about..... ☐
I have slight problems in walking about..... ☐
I have moderate problems in walking about..... ☐
I have severe problems in walking about..... ☐
I am unable to walk about..... ☐

SELF-CARE

I have no problems washing or dressing myself..... ☐
I have slight problems washing or dressing myself..... ☐
I have moderate problems washing or dressing myself..... ☐
I have severe problems washing or dressing myself..... ☐
I am unable to wash or dress myself..... ☐

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities..... ☐
I have slight problems doing my usual activities..... ☐
I have moderate problems doing my usual activities..... ☐
I have severe problems doing my usual activities..... ☐
I am unable to do my usual activities..... ☐

PAIN / DISCOMFORT

I have no pain or discomfort..... ☐
I have slight pain or discomfort..... ☐
I have moderate pain or discomfort..... ☐
I have severe pain or discomfort..... ☐
I have extreme pain or discomfort..... ☐

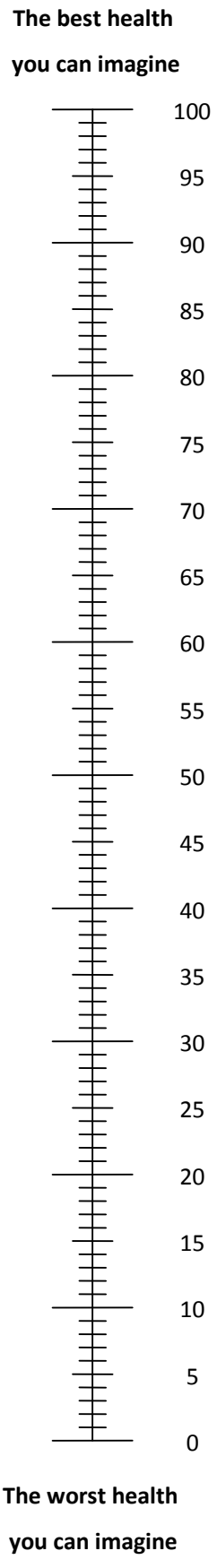
ANXIETY / DEPRESSION

I am not anxious or depressed..... ☐
I am slightly anxious or depressed..... ☐
I am moderately anxious or depressed..... ☐
I am severely anxious or depressed..... ☐
I am extremely anxious or depressed..... ☐

- We would like to know how good or bad your health is **TODAY**.
- This scale is numbered from **0** to **100**.
- **100** means the best health you can imagine.

  0 means the worst health you can imagine.
- Mark an **X** on the scale to indicate how your health is **TODAY**.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Herdman M, Gudex C, Lloyd A, Janssen MF, Kind P, Parkin D, Bonsel G, Badia X. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Quality of Life Research

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today:

1. Feeling settled and secure

I am able to feel settled and secure in **all** areas of my life..... ☐

I am able to feel settled and secure in **many** areas of my life..... ☐

I am able to feel settled and secure in **a few** areas of my life..... ☐

I am **unable** to feel settled and secure in **any** areas of my life..... ☐

2. Love, friendship and support

I can have **a lot** of love, friendship and support..... ☐

I can have **quite a lot** of love, friendship and support..... ☐

I can have **a little** love, friendship and support..... ☐

I **cannot** have **any** love, friendship and support..... ☐

3. Being independent

I am able to be **completely** independent..... ☐

I am able to be independent in **many** things..... ☐

I am able to be independent in **a few** things..... ☐

I am **unable** to be at all independent..... ☐

4. Achievement and progress

I can achieve and progress in **all** aspects of my life..... ☐

I can achieve and progress in **many** aspects of my life..... ☐

I can achieve and progress in **a few** aspects of my life..... ☐

I **cannot** achieve and progress in **any** aspects of my life..... ☐

5. Enjoyment and pleasure

I can have **a lot** of enjoyment and pleasure..... ☐

I can have **quite a lot** of enjoyment and pleasure..... ☐

I can have **a little** enjoyment and pleasure..... ☐

I **cannot** have **any** enjoyment and pleasure..... ☐

Any other comments you may have:

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This is the end of the questionnaire. Please check you have answered all questions.

Thank you for completing this questionnaire. **Please return in the Freepost envelope provided.**