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CLINICAL INVESTIGATION PLAN

STUDY TITLE:

A retrospective controlled survey-study to assess the safety of treating migraine with Nerivio during pregnancy and 3 months postpartum.

PROTOCOL NUMBER: TCH-011

REVISION: 1.0

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INVESTIGATOR: _____

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Synopsis

This is a retrospective controlled survey-study to assess the safety of treating migraine with Nerivio during pregnancy and 3 months postpartum. We will compare migraine and pregnancy related health and baby health between women with migraine who treated migraine attacks during pregnancy with Nerivio (Nerivio group), to women with migraine who did not treat migraine attacks during pregnancy with Nerivio (control group). Nerivio group participants will be recruited from Theranica's user base. Control group participants will be recruited by health care providers, including headache specialists and OBGYNs (study co-investigators). The study is fully electronic, including an e-eligibility questionnaire, an e-ICF, and an e-survey. Participants will be compensated for their time.

Goal

Assess the safety of treating migraine with Nerivio during pregnancy and 3 months postpartum.

Study Design

Retrospective controlled survey-study.

Study group: Postpartum patients with migraine who used Nerivio at least 3 times during their "study pregnancy"

Control group: Postpartum patients with migraine who did not use Nerivio during their "study pregnancy"

Eligibility

Inclusion criteria:

1. Diagnosed with migraine
2. History of migraine pre-pregnancy with an average of at least 4 migraine days per month, in the six months prior to the last pregnancy
3. History of pregnancy with last menstrual period (LMP) between November 1st, 2019 – March 31st, 2021. Pregnancy within this time window is the pregnancy of study, termed "study pregnancy"
4. Between 18 and 42 years of age at first day of the last menstrual period (LMP) of "study pregnancy"
5. History of at least 4 migraine attacks during "study pregnancy"
6. In the study group: usage of Nerivio for at least 3 treatments (≥30 minutes/treatment) during "study pregnancy"
7. In the control group: No history of using Nerivio, ever

Exclusion criteria:

1. History of preterm birth (gestational age at deliver<37 weeks) in previous pregnancies prior to the "study pregnancy"
2. History of congenital malformations or birth defects in previous pregnancies prior to the "study pregnancy"
3. Severe other diseases which started before the "study pregnancy" and lasted into the "study pregnancy" period, including congenital heart disease, arrhythmia, history of myocardial infarction (MI), history of stroke, or active cancer
4. Serious physical injury that occurred during the "study pregnancy": severe car collision injury, serious injury at home/work, etc. Multiple gestation (i.e., pregnancy with more than one baby at a time, such as pregnancy with twins, triplets, and quadruplets) in the "study pregnancy"

Study Design and Recruitment

Study group: Study group participants will be recruited from Nerivio's user base. An invitation message will be sent via in-app notification and/or email to all Nerivio users who are (1) female, AND (2) between 18 and 42 years of age as of November 1st, 2019 - March 31st, 2021. Users who meet these criteria will be invited to fill in a screening and eligibility questionnaire. If they meet the eligibility criteria, they will be offered the opportunity to participate in the study. Participants will complete and sign an electronic informed consent form. Following consent, participants will be asked to complete the questionnaire. Once complete, participants will be compensated for their time.

Control group: Control group participants will be referred to the study by site co-investigators, who are US licensed healthcare providers seeing women with headache disorders and/or women during their pre-pregnancy and/or pregnancy period. Patients interested in participating will be directed to the same screening and eligibility questionnaire and will follow the same study design.

Endpoints

Endpoints focus on the health of the mother and the baby, during pregnancy and three months postpartum.

Primary endpoint:
Demonstrate that the study group is not different than the control group in regard to gestational age at delivery (measured in pregnancy weeks).

Secondary endpoints:
Demonstrate that the study group is not different from the control group in:

1. Baby's birth weight (average birth weight)
2. Miscarriage rate (% of miscarriage cases)
3. Preterm birth rate (% cases of preterm pregnancies, as measured in % of pregnancy weeks less than 37)
4. Birth deficits rate (% of birth deficits)
5. Still births rate (% of still births)
6. Meeting developmental milestones following 3 months postnatal (% of babies)
7. Visits to the emergency room or urgent care due to pregnancy and/or migraine symptoms during pregnancy and 3 months postpartum period (# of events)

Exploratory endpoints: Difference between the study group and the control group in:

1. Overall subjective **feeling of safety** using acute migraine treatments during pregnancy (in subjects who used such treatments).
2. Overall subjective **satisfaction** with the acute migraine therapies used during the pregnancy (in subjects who used such treatments).
3. APGAR score at 5 minutes.

Data analysis

Statistical Hypothesis

The goal of the proposed study is to test the null hypothesis that treating with Nerivio during pregnancy does not impose a safety risk relative to standard care migraine treatment for pregnant women. In other words, the hypothesis is that the means of the two populations are equal. Thus, in this study, the following hypotheses will be tested:

- Null hypothesis: H0: GAt = GAc
- Alternate hypothesis: H1: GAt ≠ GAc

Where GAt and GAc are the average Gestational Age in the study group and control group, respectively. If the null hypothesis is not rejected, the study will be deemed successful. The criterion for significance has been set at 0.05. The test is 2-tailed.

Planned Sample Size

Based on USA data from 2020 [Osterman M, et al. Births: Final Data for 2020. Natl Vital Stat Rep. 2021] we assume mean gestational age (GA) of 38.4 with standard deviation of 2.7 (range 26-42).

With the proposed sample size of 114 for each group, the study will have power of 80% to yield a statistically significant result. This computation assumes that the mean difference is less than 1.0 week, and the common within-group standard deviation is 2.7. This effect was selected as the smallest effect that would be important to detect.

Precision for estimating the effect size: We further estimate the mean difference between the two populations. On average, a study of this design would enable us to report the mean difference with a precision (95% confidence level) of plus/minus 0.70 weeks.

Given this statistical requirement up to 400 participants will be recruited per group.

Statistical Analysis Plan

Data will be collected from all patients recruited to the study. Data analysis will not include patients who are:

- Obese (BMI>=40) at the beginning of the study pregnancy
- Did not have their last menstrual period (LMP) between November 1st, 2019 – March 31st, 2021
- In the study group, did not use Nerivio for at least 3 treatments (≥30 minutes/treatment) during the “study pregnancy”
- In the control group, did use Nerivio before, during, or in the 3 months following the “study pregnancy”

Appendix 1: Screening and Eligibility Procedure

Thank you for your interest in this study. We will be assessing the effect of having migraine and using Nerivio, an acute migraine treatment, on the health of mothers and babies during pregnancy and 3 months postpartum, in mothers who suffer from migraine.

To assess your eligibility for the study, please answer the following screening questions.

If you meet the eligibility criteria, you will be directed to an electronic informed consent form, followed by the study questionnaire.

Eligible participants who complete the study questionnaire will be compensated for their time, with a $100 gift card.

The following questions refer to your latest, completed, pregnancy (if you are currently pregnant, **do not** refer to the current pregnancy when answering the following questions). We will refer to that pregnancy (i.e., the completed pregnancy) as the "study pregnancy".

Page break

1. **Was your entire "study pregnancy" period (from conception to delivery) between November 1st, 2019, and March 31st, 2022?**

   - Yes
   - No

   No = not eligible

2. **Were you between 18 and 42 years of age when your "study pregnancy" began (at the date of the last menstrual period, LMP)?**

   - Yes
   - No

   No = not eligible

3. **Did the "study pregnancy" have more than one baby, such as pregnancy with twins, triplets, and quadruplets (i.e., multiple gestation pregnancy)**

   - Yes
   - No

   Yes = not eligible

4. **Have you ever diagnosed with migraine by a licensed healthcare provider?**

- Yes
- No

No = not eligible

5. **Were you <u>diagnosed</u> with migraine <u>prior</u> to your "study pregnancy"?**
   - Yes
   - No

   No = not eligible
6. **Did you have migraine attacks <u>during</u> your "study pregnancy"?**
   - Yes
   - No

   No = not eligible
7. **On average, did you have migraine at least 4 days a month, during the <u>six months prior</u> to the "study pregnancy"?**
   - Yes
   - No

   No = not eligible
8. **Did you have at least 4 migraine attacks during your "study pregnancy"?**
   - Yes
   - No

   No = not eligible
9. **<u>Did</u> you suffer from congenital heart disease, arrhythmia, history of myocardial infarction (MI), history of stroke, or active cancer <u>before/during</u> the "study pregnancy"?**
   - Yes
   - No

   Multiple choice; If Yes = not eligible
10. **Were you seriously injured <u>during</u> your "study pregnancy", e.g., had a car accident, work injury, home accident, assault, etc.?**
    - Yes

- No

Yes = not eligible

11. **Do you have a history of preterm birth (delivery at gestational age under 37 weeks) with any of your <u>previous</u> pregnancies (<u>before</u> the "study pregnancy")?**

    - Yes
    - No

    Yes = not eligible

12. **Do you have a history of congenital malformations or birth defects in any of your <u>previous</u> pregnancies (<u>before</u> the "study pregnancy")?**

    - Yes
    - No

    Yes = not eligible

Eligibility messages:

<u>Not eligible message:</u> Message presented to subjects if they do **not meet** the eligibility criteria as identified during the screening questionnaire:

Thank you for your interest in the study on migraine treatments during pregnancy.
However, the information you provided indicates that you do not meet the study eligibility requirements, and therefore cannot participate in this survey study.

<u>Eligible message:</u> Message presented to subjects upon the completion of the screening questionnaire, if they **meet** the eligibility criteria as identified during the screening questionnaire:

Thank you for your interest in the study on migraine treatments during pregnancy.
The information you provided indicates that you are eligible to participate in this survey study.
You will now be directed to an electronic informed consent form. Please read the consent form carefully. If you consent, please provide your details and electronic signature at the bottom of the consent form.

Once signed, you will be directed to the survey study questionnaire.
The questionnaire contains 52 questions. It should take approximately 30-40 min to complete the questionnaire.
In order to make it easier and faster to answer the survey questions, we recommend you prepare documents you received upon hospital discharge following delivery of your "study pregnancy", prior to answering the questionnaire.

Please select your referral clinic:

1. Clinic A
2. Clinic B
3. Clinic C
4. Clinic D
5. Clinic E
6. Other
    - Please specify _____

Single choice

Present the matching ICF, based on participant's clinic

Appendix 2: Survey Questionnaire

This questionnaire asks about your general health with a focus on your migraine, your health during and after your "study pregnancy", and about your child's health.

Please refer to your latest, completed, pregnancy (if you are currently pregnant, please do not refer to the current pregnancy when answering the following questions). We will refer to the latest, completed, pregnancy as the "study pregnancy".

It will take approximately 30-40 minutes to complete the questionnaire.

Part 1 – Demographics and medical history prior to "study pregnancy"

1. **What is your date of birth?**

   Mark on Calendar

2. **Are you of Hispanic, Latino, or of Spanish origin?**

   - Yes
   - No

3. **How would you describe yourself?**

   - American Indian or Alaska Native
   - Asian
   - Black or African American
   - Hispanic or Latino
   - Native Hawaiian or Other Pacific Islander
   - White or Caucasian
   - Other

4. **What is your height (feet, inches)**

   Choose: Pull down menu between 4.0 to 7.0 with 0.1 jumps. Allow other.

5. **Weight (lb) at the beginning of your study pregnancy**

   Choose: Pull down menu between 85 and 300 lb, with jumps of 5 units. Allow other.

6. **Do you have a history of any of the following medical conditions, that was diagnosed prior to your study pregnancy? Check all that apply**

- AIDS/HIV
- Anemia
- Asthma
- Autoimmune disease (such as lupus, rheumatoid arthritis etc)
- Clinically diagnosed depression or any other psychiatric diseases
- Clinical obesity (body mass index, BMI, greater than 30)
- Endometriosis
- Epilepsy
- Kidney disease
- High blood pressure
- Pre-pregnancy diabetes
- Polycystic ovary syndrome (PCOS)
- Sexually transmitted disorders
- Thyroid disease
- Other diseases
    - Please specify _____

Check all that applies

7. **Prior to your "study pregnancy", do you have a history of (Check <u>all that applies</u>)**

    - Smoking
    - Excessive alcohol consumption (more than 1 glass of wine/day or any other alcohol equivalent)
    - Using medical marijuana
    - Using recreational drugs

    Multiple choice

8. **On average, how many days per month did you experience migraine in the <u>6 months prior</u> to the "study pregnancy"?**

    - Less than 4 days per month
    - 4-8 days per a month

- 9-14 days per month
- 15 days or more per month

Multiple choice

9. **How often did you use <u>acute</u> treatments for migraine (either pharmaceutical drugs and/or devices) in the <u>six months prior</u> to the "study pregnancy"?**

   - Less than 4 times per month
   - 4-8 times per a month
   - 9-14 times per month
   - 15 times or more per month

   Multiple choice

10. **Please read carefully and mark <u>all</u> types of <u>ACUTE</u> treatments (either pharmaceutical drugs and/or devices) you used for migraine <u>in the six months prior to the study</u> pregnancy. Please include any treatment, even if used only once. In cases where two names are used, one is the generic name and one is the branded name (Check <u>all that applies</u>)**

    - Tylenol®, or any other acetaminophen/paracetamol
    - Excedrin® (Aspirin and paracetamol and caffeine) -
    - Advil®, Motrin®, or any other ibuprofen
    - Aleve®, Anaprox®, or any other Naproxen sodium
    - Other over-the-counter medications
    - Cambia® (Diclofenac)
    - Cafergot®, Ergomar® (Ergotamines)
    - Tivorbex® (Indomethacin)
    - Imitrex® (sumatriptan)
    - Maxalt® (rizatriptan)
    - Relpax® (Eletriptan)
    - Treximet® (sumatriptan/naproxen sodium)
    - Axert (Almotriptan), Zomig® (zolmitriptan)
    - Other Oral Triptan

- Nurtec® ODT (Rimegepant)
- Ubrelvy® (Ubrogepant)
- Tosymra® (sumatriptan nasal spray)
- Onzetra Xsail® (sumatriptan nasal poder)
- Zembrace SymTouch® (sumatriptan injection)
- Zomig® nasal spray (Zolmitriptan)
- Migranal® (Dihydroergotamine Mesylate Spray)
- Trudhesa™ (dihydroergotamine mesylate nasal spray)
- Other nasal / injectable medication
- Reyvow (Lasmiditan®)
- Nerivio® (Remote Electrical Neuromodulation)
- Other devices (e.g., gammaCore™, Cefaly®, Relivion®)
- Zofran® (Ondansetron)
- Reglan® (Metoclopramide)
- Compazine® (Prochlorperazine)
- Phenergan® (Promethazine)
- Other medication for nausea/vomiting
- Other medications
- None

Check all that applies

11. **Please mark the <u>PREVENTIVE</u> migraine treatment (either pharmaceutical drugs and/or devices) you used during the <u>six months prior to the study</u> pregnancy. (Check all that applies)**

    - Amitriptyline, or any other generic tricyclic antidepressants
    - Inderal® (Propranolol)
    - Topiramate® (Topamax)
    - Other generic oral preventive medication
    - Nortriptyline (Pamelor), or any othernon-generic tricyclic antidepressants

- Botox® injection for migraine prevention (Botulinum toxin)
- Aimovig® (Erenumab)
- Ajovy® (Fremanezumab)
- Emgality® (galcanezumab-gnlm)
- Vyepti® (eptinezumab-jjmr)
- Nurtec® ODT (Rimegepant)
- Devices (e.g., gammaCore, Cefaly)
- Other
- Did not use any preventive treatment

Check all that applies

12. **Have you been diagnosed with migraine with aura by a licensed healthcare provider? (Aura is a neurologic symptom that occurs typically before or during migraine that lasts 5-60 minutes and is characterized by an evolution of neurologic symptoms such as flashing lights or colors that grow in your visual field)**

    - Yes
    - No

13. **Do you usually experience aura right before your headache attacks?**

    - Always
    - Sometimes
    - Never

14. **Have you ever used Nerivio® to treat your migraine attacks?**

    - Yes
    - No

15. **How many prior pregnancies before the "study pregnancy" have you had?**

    Choose from 0 to 10 and "more than 10"

16. **How many of these were completed pregnancies?**

Show question if >0 in the previous question. Responses: Choose from 0 to 10 and "more than 10"

17. **Is there a family history of congenital defects or malformations?**
    - Yes
    - No

Part 2 – Study pregnancy

The following questions refer to you latest, completed, pregnancy, termed "study pregnancy" (if you are currently pregnant, please do not refer to this pregnancy when answering the questionnaire).

18. **What was the first day of the last menstrual period (LMP) before your "study pregnancy"? (Please provide accurate month and year. If you do not recall the exact day within the month, please choose 1st day of the month).**
    - Choose on calendar / enter date (month, year; day is optional)

    Year and month are good enough. Day is optional.

19. **What was the delivery date of your "study pregnancy"?**
    - Choose on calendar

20. **What was your baby's gestational age at delivery or at the end of pregnancy (pregnancy length measured by number of weeks and days) of your "study pregnancy"**

    Choose on "roller", allow weeks (6 to 42 weeks) and days (+0 to 6 days). If possible, allow weeks and days separately..

21. **What is the status of your "study pregnancy"?**
    - Live birth
    - Elective termination
    - Spontaneous abortion (or miscarriage)
    - Late fetal death

22. **If you had a miscarriage, what was its cause?**
    - I did not experience a miscarriage
    - Abnormal fetal development

- Abnormal placenta (such as abruption)
- Blood disorders such as thrombophilias
- Cervical insufficiency
- Chromosomal abnormalities
- Maternal anatomic abnormalities such as uterine fibroids, polyps or adhesions in uterus
- Physical trauma
- Unknown cause
- Other

23. Delivery circumstances (Check all that applies)

- Spontaneous labor
- Induction of labor
- Past due date
- Decreased fetal movement
- Cardiac arrhythmia in fetus
- Pregnancy induced hypertension such as gestational hypertension or pre-eclampsia
- HELLP syndrome
- Premature rupture of membranes
- Other complications or medical concerns

Check all that apply

24. What was the mode of delivery?

- Repeat Cesarean Delivery
- Primary Cesarean delivery
- Spontaneous vaginal delivery

25. During your "study pregnancy", did you do any of the following (select all that apply)

- Smoking

- Excessively consuming alcohol (more than 1 glass of wine/day or any other equivalent)
- Using medical marijuana
- Using recreational drugs

Check all that apply

26. Was the baby discharged from the hospital at the same time with you?

- Yes
- No

27. Did you use Nerivio to treat your migraine attacks during your "study pregnancy"?

- Yes
- No

28. <u>During</u> your "study pregnancy", did you use Nerivio for migraine treatment <u>at least 3 times?</u>

- Yes
- No

Part 3 – Migraine during the study pregnancy

The following questions refer to your <u>latest</u>, completed, pregnancy referred to as the "<u>study</u> pregnancy" (if you are currently pregnant, please do not refer to this pregnancy when answering the questionnaire).

29. How many migraine days per month (on average) did you have during the FIRST trimester of your "study pregnancy"?

- Less than 4 days per month
- 4-8 days per a month
- 9-14 days per month
- 15 days or more per month

Multiple choice

30. How often did you use <u>ACUTE</u> treatments for migraine during the FIRST trimester of your "study pregnancy"?

- Less than 4 times per month
- 4-8 times per a month
- 9-14 times per month
- 15 times or more per month

Multiple choice

31. **How many migraine days per month (on average) did you have during the SECOND trimester of your "study pregnancy"?**
    - Less than 4 days per month
    - 4-8 days per a month
    - 9-14 days per month
    - 15 days or more per month

    Multiple choice
32. **How often did you use <u>ACUTE</u> treatments for migraine during the SECOND trimester of your "study pregnancy"?**
    - Less than 4 times per month
    - 4-8 times per a month
    - 9-14 times per month
    - 15 times or more per month

    Multiple choice
33. **How many migraine days per month (on average) did you have during the THIRD trimester of your "study pregnancy"?**
    - Less than 4 days per month
    - 4-8 days per a month
    - 9-14 days per month
    - 15 days or more per month

    Multiple choice
34. **How often did you use <u>ACUTE</u> treatments for migraine during the THIRD trimester of your "study pregnancy"?**
    - Less than 4 times per month

- 4-8 times per a month
- 9-14 times per month
- 15 times or more per month

Multiple choice

35. Please mark <u>all</u> types of <u>ACUTE</u> treatments (either pharmaceutical drugs and/or devices) you used for migraine <u>during</u> the "study pregnancy". Please include any treatment, even if used only once.

For each treatment type used, please indicate if you felt SAFE using it during the <u>pregnancy</u> by choosing the matching option of the dropdown menu.

- Tylenol®, or any other acetaminophen/paracetamol

  Did you feel safe using this medication during the pregnancy?
  - Yes
  - No
- Excedrin® (Aspirin and paracetamol and caffeine) -
- Advil®, Motrin®, or any other ibuprofen
- Aleve®, Anaprox®, or any other Naproxen sodium
- Other over-the-counter medications
- Cambia® (Diclofenac)
- Cafergot®, Ergomar® (Ergotamines)
- Tivorbex® (Indomethacin)
- Imitrex® (sumatriptan), Maxalt® (rizatriptan), Relpax® (Eletriptan), Treximet® (sumatriptan/naproxen sodium), Axert (Almotriptan), Zomig® (zolmitriptan), or any other Oral Triptan
- Nurtec® ODT (Rimegepant)
- Ubrelvy® (Ubrogepant)
- Tosymra® (sumatriptan nasal spray), Onzetra Xsail® (sumatriptan nasal poder), Zembrace SymTouch® (sumatriptan injection); Zomig® nasal spray (Zolmitriptan), Migranal® (Dihydroergotamine Mesylate Spray); Trudhesa™ (dihydroergotamine mesylate nasal spray), or any other nasal / injectable medication
- Reyvow (Lasmiditan®)
- Nerivio® (Remote Electrical Neuromodulation)

- Other devices (e.g., gammaCore™, Cefaly®, Relivion®)
- Zofran® (Ondansetron), Reglan® (Metoclopramide), Compazine® (Prochlorperazine), Phenergan® (Promethazine), or any other medication for nausea/vomiting
- Other medications
- None

Check all that applies

36. **Rate your <u>overall satisfaction</u> with your <u>acute</u> migraine treatment during your "study pregnancy", when 1 = Highly dissatisfied, 10 = Highly satisfied**

    Drop Down menu, with <u>options 1-to-10</u> AND <u>Not relevant (I did not use acute migraine treatment during my pregnancy)</u>

37. **Please mark <u>all</u> types of <u>PREVENTIVE</u> treatments (either pharmaceutical drugs and/or devices) you used for migraine <u>during</u> the "study pregnancy". Please include any treatment, even if used only once.**

    For each treatment type used, please indicate if you felt safe using it during the <u>pregnancy</u> by choosing the matching option of the dropdown menu.
    - Amitriptyline, or any other generic tricyclic antidepressants
    - Inderal® (Propranolol)
    - Topiramate® (Topamax)
    - Other generic oral preventive medication
    - Nortriptyline (Pamelor), or any othernon-generic tricyclic antidepressants
    - Botox® injection for migraine prevention (Botulinum toxin)Aimovig® (Erenumab), Ajovy® (Fremanezumab), Emgality® (galcanezumab-gnlm), Vyepti® (eptinezumab-jjmr) , that is any CGRP monoclonal antibodies (CGRP mAbs)
    - Nurtec® ODT (Rimegepant)
    - Devices (e.g., gammaCore, Cefaly)
    - Other
    - Did not use any preventive treatment

38. **Rate your <u>overall satisfaction</u> with your <u>PREVENTIVE</u> migraine treatment during your "study pregnancy", when 1 = Highly dissatisfied, 10 = Highly satisfied**

    Drop Down menu, with <u>options 1-to-10</u> AND <u>Not relevant (I did not use preventive migraine treatment during my pregnancy)</u>

39. **Were you admitted to the emergency room (ER) or hospital for management/evaluation of headache during your "study pregnancy"?**
    - Yes
    - No

Part 4 – Migraine postpartum

40. **How many migraine days per month (on average) did you have in the <u>3 months postpartum</u> after your "study pregnancy"?**
    - Less than 4 days per month
    - 4-8 days per a month
    - 9-14 days per month
    - 15 days or more per month

41. **Did you breast-feed during the first 3 months postpartum following your "study pregnancy"?**
    - Yes
    - No

Part 5 – Baby's health

42. **For your "study pregnancy", what is your baby's sex at birth?**
    - Male
    - Female

43. **What was the baby's birth weight (lbs)?**

    Choose on a drop-down menu, including the following answers:
    - Less than 1.5 kg / 3.4 pounds
    - Between 1.5 and 2.49 kg / between 3 pounds 4 ounces and 5 pounds 8 ounces
    - Weights with jumps of 100 gram up to 4 kg and the equivalent in pounds (2.5, 2.6, 2.7, …. 4)
    - More than 4 kg / 8 pounds and 13 ounces

44. Was the baby diagnosed with any birth defects?

- No
- Yes

45. Were there any complications with the baby after delivery?

- No
- Yes

If Yes, what type of complication?

- Neonatal jaundice, ….
- Newborn required admission to the neonatal intensive care unit
- Respiratory distress syndrome
- Infection such as sepsis
- Failure to thrive
- Low birth weight
- Other

46. Did your baby meet routine developmental milestones at <u>3 months?</u> of life (such as smiling, gurgle, visually tracking objects, and rolling over within the first 3 months)

- No
- Yes

47. What was your baby's APGAR scores at <u>1 minute</u> after birth?

We know it might be difficult to remember this score. Please check your discharge notes to find the 1 minute APGAR score, although not all notes include this information:

- Choose 1-10
- Don't know / Can't find the 5 min APGAR score

Use a dropdown menu, and add the option can't find

48. What was your baby's APGAR scores <u>5 minutes</u> after birth? We know it might be difficult to remember this score. Please check your discharge notes to find the 5 minutes APGAR score, although not all notes include this information:

- Choose 1-10
- Don't know / Can't find the 5 min APGAR score

Use a dropdown menu, and add the option can't find

49. **Does the baby have any additional APGAR scores at 10, 15 or 20 minutes?**
    - Yes
    - No
    - Don't know

    If Yes, go to the next page, and ask for APGAR scores at 3 additional time points. Otherwise (answer: No or Don't know), go directly to the last page.

Page break

50. **What was your baby's APGAR scores <u>10 minutes</u> after birth? We know it might be difficult to remember this score. Please check your discharge notes to find the 5 minutes APGAR score:**
    - Choose 1-10
    - Don't know / Can't find the 5 min APGAR score

51. **What was your baby's APGAR scores <u>15 minutes</u> after birth? We know it might be difficult to remember this score. Please check your discharge notes to find the 5 minutes APGAR score:**
    - Choose 1-10
    - Don't know / Can't find the 5 min APGAR score

52. **What was your baby's APGAR scores <u>20 minutes</u> after birth? We know it might be difficult to remember this score. Please check your discharge notes to find the 5 minutes APGAR score:**
    - Choose 1-10
    - Don't know / Can't find the 5 min APGAR score

Page break

Thank you for your participation in this study. The payment will be sent to your email following the verification of your participation with the clinic (approximately 48 hours). Please contact tch011@theranica.com if you did not receive the payment within this time.