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Supplemental file 2

Informed consent

Dear subject's guardian:

We invite your baby to participate in a study on "Establishing the reference interval for pulse oxygen saturation in neonates at high altitudes." This study will be jointly carried out in Qinghai Women and Children's Hospital, Qinghai Red Cross Hospital, and other hospitals. It is estimated that 10,000 infants will participate voluntarily. This study has been reviewed and approved by the Medical Ethics Committee of Qinghai Women and Children's Hospital.

Why is this study conducted? Establishing the reference interval for pulse oxygen saturation (SpO_2) is essential for sensitively identifying neonatal hypoxemia triggered by various causes. However, the reference interval for high altitudes has not been established yet, and the existing studies have many limitations, such as inadequate selection of study participants. This situation is unfavorable for medical decision-making and nursing work. This study aims to establish the reference intervals for a range of high altitudes.

What do I need to do if I participate in the study? If you are willing to let your baby participate in this study, you need to authorize us to extract the basic information of your baby and his/her mother from the medical records and measure the SpO_2 24 hours after birth for this clinical study. The basic information will include the baby's mother's name, age, hospitalization number, hospitalization date, home address, telephone number, and ethnicity. We will also retrieve the baby's name, date of birth, gestational age, sex, mode of delivery, birth weight, and Apgar scores (1 and 5 minutes).

Who should not participate in the study? If your baby is in the following circumstances, it will not be within the scope of this study: 1. Low birth weight (<2,500 g). 2. Need for oxygen. 3. Apgar score < 7 at 1 or 5 minutes. 4. Referred to neonatal intensive care unit or neonatology department for any reason. 5. Discharged within 24 hours of birth. 6. With confirmed congenital disease in utero. 7. If you refuse participation.

What are the risks of participating in the study? The monitoring of SpO_2 is a non-invasive nursing method. Its purpose is to identify hypoxemia triggered by various causes early. If the sensor is tied too tightly or the binding time is too long, it might result in skin crush. However, the measurement time in our study is very short, and all measurement personnel are strictly trained, so this risk is very small.

What are the benefits of participating in the study? Your baby will not get additional benefits by participating in this study, but the study results will promote the development of neonatal medicine and provide a basis for better medical decision-making and nursing for future babies.

Do I need to pay to participate in the study? We will not charge additional fees for participating in this study, and we will not pay any fees to guardians participating in the project.

Is personal information confidential? Your medical records will be kept in the hospital, and researchers, research authorities, and the ethics committee will be allowed access to them. Any public report on the results of this study will not disclose your identity. We will make every effort to protect the privacy of your medical data to the extent indicated by law.

Do I have to take part in the study? Participation in this study is completely voluntary. You candecline participation or withdraw from the study at any time during its course, with no effect on the

care of your baby by the healthcare workers.

Subject's Guardian statement: I have read the above introduction to this study and understand the risks and benefits of participating in this study. I volunteer to participate in this study.

Office of medical ethics committee Tel: _____

I agree ☐ I reject ☐

Signature of the subject's Guardian:_____ Date:_____

Contact number of the subject's Guardian: _____ Mobile phone number: _____

Doctor's statement: I confirm that I have explained the details of this study to the guardian, especially the possible risks and benefits of participating in this study.

Doctor's signature:_____ Date:_____

Doctor's contact number: _____ Mobile phone number: _____

Hospital Name:_____

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Chinese version

知情同意书

尊敬的受试者监护人

我们邀请您的宝宝参加 “建立高海拔地区新生儿脉搏血氧饱和度的参考区间”课题研究。本研究将在青海妇女儿童医院、青海红十字医院等医院共同开展，估计将有 10000 名受试者自愿参加。本研究已经得到青海妇女儿童医院医学伦理委员会的审查和批准。

为什么要开展本项研究？建立新生儿脉搏血氧饱和度的参考区间对敏锐识别因各种病因引起的低氧血症至关重要。然而，目前在高海拔地区尚未建立参考区间。并且现有的研究存在许多局限性，如选取的对象不合理等。这个现状不利于医疗决策和护理工作的开展。本研究的目的是建立高海拔地区各个高度的新生儿出生 24h 以后的脉搏血氧饱和度的参考区间。

如果参加研究，需要做什么？如果您愿意参加本项研究，您需要授权同意我们提取新生儿及母亲的基本信息以及新生儿出生 24h 后的脉搏血氧饱和度的测量数据进行临床研究。基本信息具体为：母亲的姓名，年龄，住院号，住院日期，家庭住址，手机号码，民族。 新生儿的姓名、出生日期、胎龄、性别、分娩方式、出生体重、Apgar 评分（1 分钟、5 分钟）。

哪些人不宜参加研究?如果您的宝宝属于以下情况则不属于此项研究范围：1.低出生体重(<2500g)，2.需要吸氧，3.1 或 5 分钟 Apgar 评分<7，4.出生后因各种原因转至新生儿重症监护室或新生儿科的新生儿。5.出生后 24 小时内出院的新生儿。6.宫内已确诊患先天性疾病的新生儿。7.拒绝同意。

参加研究有哪些风险？脉搏血氧饱和度的监测是一种无创的护理手段。目的是早期识别因各种病因导致的低氧血症。可能的风险是传感器捆绑过紧或者捆绑时间过长导致皮肤压伤，但是我们的研究所测量的时间很短，且所有的测量人员都是经过严格的培训，所以这种风险极小。

参加研究有哪些好处？参加本项研究，您的宝宝不会额外获得好处，但这些研究的结果将会促进新生儿医学的发展，为以后新出生的宝宝提供更好的医疗决策和护理提供依据。

参加研究需要支付有关费用吗？我们不会因参与本研究而额外收取费用，同时也不给予参与课题的监护人支付额外费用。

个人信息是保密的吗？您的医疗记录将保存在医院，研究者、研究主管部门、伦理委员会将被允许查阅您的医疗记录。任何有关本项研究结果的公开报告将不会披露您的个人身份。我们将在法律允许的范围内，尽一切努力保护您个人医疗资料的隐私。

我必须参加研究吗？参加本项研究是完全自愿的，您可以拒绝参加研究，或在研究过程中的任何时间退出本研究，这都不会影响医护人员对您的宝宝的护理。

受试者监护人声明：我已经阅读了上述有关本研究的介绍，对参加本研究可能产生的风险和受益充分了解。我自愿参加本研究。

医学伦理委员会办公室电话：

我同意☐ 或拒绝☐

受试者监护人签名：_____ 日期：__ __ __ __ 年 __ __ 月 __ __ 日

受试者监护人联系电话：_____ 手机号：_____

医生声明：我确认已向患者解释了本研究的详细情况，特别是参加本研究可能产生的风险和受益。

医生签名：_____ 日期：__ __ __ __ 年 __ __ 月 __ __ 日

医生的工作电话：_____ 手机号：_____

医院名称：_____