

Clinical trial registration statement

Name of journal: *World Journal of Diabetes*

Manuscript NO: 78290

Title: Solid-phase Microextraction Gas Chromatography/Mass Spectrometry Metabonomics Fingerprint of Volatile Organic Carbons in Serum and Urine of Pregnant Women with Gestational Diabetes Mellitus

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This study is registered with the Chinese Clinical Trial Registry (registration number: ChiCTR2000038703).

Enyou Li

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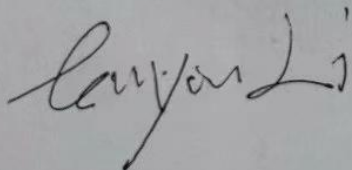
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Enyou Li

A handwritten signature in black ink, appearing to read 'Enyou Li', is written below the printed name.



萨那斯日古楞医师: 请与我们联系上传审批文件并填写伦理审批日期。围产期妊娠糖尿病与认知功能障碍相关性的研究

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注册号: ChiCTR2000038703
Registration number:
最近更新日期: 2020-12-14
Date of Last Refreshed on:
注册时间: 2020-09-29
Date of Registration:
注册号状态: 预注册
Registration Status: Prospective registration
注册题目: 萨那斯日古楞医师: 请与我们联系上传审批文件并填写伦理审批日期。围产期妊娠糖尿病与认知功能障碍相关性的研究
Public title: Maternal Mild Cognitive Impairment during Pregnancy in Relation to Gestational Diabetes Mellitus
注册题目缩写:
English Acronym:
研究课题的正式科学名称: 围产期妊娠糖尿病与认知功能障碍相关性的研究
Scientific title: Maternal Mild Cognitive Impairment during Pregnancy in Relation to Gestational Diabetes Mellitus
研究课题代号(代码):
Study subject ID:
在二级注册机构或其它机构的注册号:
The registration number of the Partner Registry or other register:

申请注册联系人: 萨那斯日古楞	研究负责人: 李恩友
Applicant: Sa na si ri gu leng	Study leader: En-You Li
申请注册联系人电话: +86 18845765101	研究负责人电话: +86 13845109928
Applicant telephone:	Study leader's telephone:
申请注册联系人传真:	研究负责人传真:
Applicant Fax:	Study leader's fax:
申请注册联系人电子邮件: sana820816@163.com	研究负责人电子邮件: enyouli@sina.com
Applicant E-mail:	Study leader's E-mail:
申请单位网站(自愿提供):	研究负责人网站(自愿提供):
Applicant website(voluntary supply):	Study leader's website(voluntary supply):
申请注册联系人通讯地址: 哈尔滨市邮政街23号	研究负责人通讯地址: 哈尔滨市邮政街23号哈尔滨医科大学附属第一医院 麻醉科
Applicant address: 23 Youzheng Street, Harbin, Heilongjiang, China	Study leader's address: 23 Youzheng Street, Harbin, Heilongjiang, China
申请注册联系人邮政编码:	研究负责人邮政编码:
Applicant postcode:	Study leader's postcode:
申请人所在单位: 哈尔滨医科大学附属第一医院	
Applicant's institution: The First Affiliated of Harbin Medical University	

是否获伦理委员会批准: 是
Approved by ethic committee: Yes
伦理委员会批件文号: 2019120
Approved No. of ethic committee:
批准本研究的伦理委员会名称: 哈尔滨医科大学附属第一医院伦理委员会
Name of the ethic committee: The First Affiliated of Harbin Medical University
伦理委员会批准日期:
Date of approved by ethic committee:
伦理委员会联系人: 鲍美汐
Contact Name of the ethic committee: Mei xi Bao

伦理委员会批件附件:
Approved file of Ethical Committee:

研究设计:	析因分组 (即根据危险因素或暴露因素分组)		
Study design:	Factorial		
纳入标准:	健康孕妇及妊娠期糖尿病孕妇, 年龄大于18-35岁, ASA-II级		
Inclusion criteria:	Patients aged 18-35 years with American Society of Anaesthesiologists(ASA) physical status I - II were admitted to the study		
排除标准:	<p>孕前既往有糖尿病, 先兆子痫, 羊水过多, 任何慢性疾病, 胎儿畸形, 肾疾病, 肝疾病, 多胎妊娠。</p> <p>Subjects on medications affecting cognitive functions including corticosteroids, anti-depressants or anti-epileptics were also not included. Additionally, subjects suffering from any chronic metabolic, endocrine, inflammatory or infectious diseases, cancer and subjects who had drug or alcohol dependency, history of major brain abnormalities (e.g. tumors, hydrocephaly), epilepsy, Parkinsons disease or stroke.</p>		
研究实施时间:	从From 2020-09-01至To 2020-10-30	征募观察对象时间:	从From 2020-10-01至To 2020-11-16
Study execute time:		Recruiting time:	
组别:	正常孕妇组和GDM组	样本量:	80
Group:	P group and G group	Sample size:	
干预措施:	抽取3MI血液样本	干预措施代码:	
Interventions:		Intervention code:	
Intervention:	blood 3 ml		
国家:	中国	省(直辖市):	黑龙江
Country:	China	Province:	Heilongjiang
市(区县):		City:	
研究实施地点:	单位(医院): 哈尔滨医科大学附属第一医院	单位级别:	三甲医院
Countries of recruitment and research settings:			
Institution hospital:	The First Affiliated of Harbin Medical University	Level of the institution:	Tertiary A Hospital
指标中文名:	二肽基肽酶4	指标类型:	主要指标
Outcome:	DPP4	Type:	Primary indicator
测量时间点:		测量方法:	
Measure time point of outcome:		Measure method:	
测量指标:	指标中文名: MOCA量表	指标类型:	次要指标
Outcomes:		Type:	Secondary indicator
Outcome:	MOCA		
伦理委员会联系地址:	哈尔滨医科大学附属第一医院		
Contact Address of the ethic committee:	The First Affiliated of Harbin Medical University, 23 Youzheng Street, Haerbin, Heilongjiang, China		
伦理委员会联系人电话:		伦理委员会联系人邮箱:	
Contact phone of the ethic committee:		Contact email of the ethic committee:	
研究实施负责(组长)单位:	哈尔滨医科大学		
Primary sponsor:	The First Affiliated of Harbin Medical University		
研究实施负责(组长)单位地址:	哈尔滨医科大学		
Primary sponsor's address:	23 Youzheng Street, Haerbin, Heilongjiang, China		
国家:	中国	省(直辖市):	黑龙江
Country:	China	Province:	Heilongjiang
市(区县):		City:	
试验主办单位(项目批准或申办者):	单位(医院): 哈尔滨医科大学附属第一医院	具体地址:	邮政街23号
Secondary sponsor:			
Institution hospital:	The First Affiliated of Harbin Medical University	Address:	23 Youzheng Street, Haerbin
经费或物资来源:	无		
Source(s) of funding:	NO		
研究疾病:	妊娠期糖尿病		
Target disease:	GDM		
研究疾病代码:			
Target disease code:			
研究类型:	观察性研究		
Study type:	Observational study		
研究所处阶段:	I期临床试验		
Study phase:	1		
研究目的:	围产期妊娠期糖尿病与轻度认知功能障碍相关性的研究		
Objectives of Study:	Maternal Mild Cognitive Impairment during Pregnancy in Relation to Gestational Diabetes Mellitus		

测量指标: Outcomes:	Outcome: 指标中文名: MOCA量表 Outcome: MOCA 测量时间点: Measure time point of outcome:	指标类型: 次要指标 Type: Secondary Indicator 测量方法: Measure method:
采集人体标本: Collecting sample(s) from participants:	标本中文名: 血液 Sample Name: blood 人体标本去向: 使用后销毁 Fate of sample: Destruction after use	组织: Tissue: 说明: Note:
征募研究对象情况: Recruiting status:	正在进行 Recruiting	年龄范围: Participant age: 最小 Min age 18 岁 years 最大 Max age 35 岁 years
性别: Gender:	女性 Female	
随机方法 (请说明由何人用什么方法产生随机序列): Randomization Procedure (please state who generates the random number sequence and by what method):	No No	
盲法: Blinding:	N/A N/A	
原始数据公开时间: The time of sharing IPD:	试验完成后6个月内公开/Within six months after the trial complete	
共享原始数据的方式 (说明: 请填写公开原始数据日期和方式, 如采用网络平台, 需填该平台名称和网址): The way of sharing IPD (include metadata and protocol, If use web-based public database, please provide the url):	2020-10月共享原始数据 2020-october sharing of raw data	
数据采集和管理 (说明: 数据采集和管理由两部分组成, 一为病例记录表 (Case Record Form, CRF), 二为电子采集和管理系统 (Electronic Data Capture, EDC), 如ResMan 即为一种基于互联网的EDC: Data collection and Management (A standard data collection and management system include a CRF and an electronic data capture:	病例记录为主 It's mostly case history	
数据管理委员会: Data Management Committee:	有/Yes	

返回列表